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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

KIM ALLEN, DANIELE XENOS, ROGER HUTCHINSON, MELISSA NIGH, SHERRELL SMITH, YUANKE XU, DIANA SISTI, and NANCY RODRIGUEZ on behalf of themselves, all others similarly situated, and the general public,

Plaintiffs,

v.

HYLAND'S, INC., a California Corporation; and STANDARD HOMEOPATHIC COMPANY,

Defendants.

Case No. 3:12-cv-1150-DMG (MAN)
CLASS ACTION
Filed: February 9, 2012

THIRD AMENDED COMPLAINT FOR:

1) **VIOLATION OF THE CONSUMERS LEGAL REMEDIES ACT, CAL. CIV. CODE §§ 1750, *et seq.*;**

2) **VIOLATION OF THE UNFAIR COMPETITION LAW, CAL. BUS. & PROF. CODE §§ 17200, *et seq.*;**

3) **VIOLATION OF THE FALSE ADVERTISING LAW, CAL. BUS. &**

PROF. CODE §§ 17500, *et seq.*;

4) BREACH OF EXPRESS WARRANTY;

5) BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY;

6) VIOLATION OF MAGNUSON-MOSS ACT, 15 U.S.C. §§ 2301, *et. seq.*;

7) VIOLATION OF FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT, Fla. Stat. Ann. §§ 501 201, *et seq.;*

8) VIOLATION OF GEORGIA UNIFORM DECEPTIVE TRADE PRACTICE ACT, Ga. Code Ann. §§ 10-1-391(a), *et seq.*

DEMAND FOR JURY TRIAL

INTRODUCTION

1. Plaintiffs Kim Allen, Daniele Xenos, Melissa Nigh, Sherrell Smith, Yuanke Xu, Diana Sisti and Nancy Rodriguez on behalf of themselves, all others similarly situated, and the general public ("Plaintiffs"), allege against defendants Hyland's, Inc., and Standard Homeopathic Corporation (collectively, "Defendants") as follows:

2. Defendants are the manufacturers and sellers of homeopathic products that are falsely and deceptively advertised, as set forth herein. This complaint concerns twelve of Defendants' homeopathic products, known as Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets, Colic Tablets, Leg Cramps with Quinine, Leg Cramps, Defend Cold & Cough, Defend Cold & Cough Night, Hyland's Cough, and Seasonal Allergy Relief (collectively referred to herein as the "Products"). Ex. 1 (photos of Products' packaging).

JURISDICTION AND VENUE

3. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2), as amended by the Class Action Fairness Act of 2005, because the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $5,000,000 and is a class action in which some members of the class are citizens of states different than Defendants. This Court also has original jurisdiction over the federal claims under the Magnuson-Moss Warranty Act pursuant to 28 U.S.C. § 1331. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367. Further, greater than two-thirds of the class members reside in states other than the states in which Defendants are citizens.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because many of the acts and transactions, including the purchases and sales giving rise to this action, occurred in this district and because Defendants (i) are authorized to conduct business in this district and have intentionally availed themselves of the laws and

markets within this district through the promotion, marketing, distribution and sale of its Products in this district; (ii) do substantial business in this district; (iii) advertise to consumers residing in this district, and (iv) are subject to personal jurisdiction in this district.

THE PARTIES

5. Plaintiff Kim Allen is a resident of Sarasota, Florida.

6. Plaintiff Daniele Xenos is a resident of Decatur, Georgia.

7. Plaintiff Melissa Nigh is a resident of Morgan Hill, California.

8. Plaintiff Sherrell Smith is a resident of Vista, California.

9. Plaintiff Yuanke Xu is a resident of Oceanside, California.

10. Plaintiff Diana Sisti is a resident of San Diego, California.

11. Plaintiff Nancy Rodriguez is a resident of Ormond Beach, Florida.

12. Defendant Hyland's, Inc. is a California corporation that maintains its principal place of business in the County of Los Angeles, California.

13. Defendant Standard Homeopathic Company is a Nevada corporation and the parent corporation of Hyland's, Inc. that maintains its principal place of business in the County of Los Angeles, California.

14. Plaintiffs are informed and believe and thereon allege that, at all times herein mentioned, the Defendants and Defendants' employees were the agents, servants and employees of the Defendants, acting within the purpose and scope of that agency and employment.

15. Defendants produce, market, and sell homeopathic Products throughout the United States. Defendants have long maintained substantial manufacturing, distribution, marketing and warehousing operations in Los Angeles, California. Defendants' formulation, labeling and marketing decisions regarding the Products occurred in Los Angeles, California.

FACTUAL BACKGROUND

16. Homeopathy seeks to stimulate the body's ability to heal itself by giving very small doses of highly diluted substances. However, there is "little evidence" that homeopathy is effective, much less that people understand homeopathic dilution principles. *See* nccam.nih.gov/sites/nccam.nih.gov/files/ homeopathy.pdf.

17. Homeopathy is premised on two main principles; the principle of similars and the principle of dilutions. Under the "principle of similars" a disease can be cured by a substance that produces similar symptoms in healthy people. Thus, homeopathic drugs are intended to work by causing "aggravation," or a temporary worsening of symptoms initially, a fact that is not communicated to consumers. *See id.*

18. Under the "principle of dilutions" the *lower* the dose of the medication, the *greater* its effectiveness. However, it is paradoxical that through dilution an ingredient would reach higher potency. Further, in highly diluted remedies, there is a very low probability that even a single molecule of the original substance is present in the Product. For example, a level of 12C dilution is the equivalent to a pinch of salt in both the North and South Atlantic Oceans.[1]

19. Homeopathic remedies are not marketed and sold in the United States in the same manner as when they first originated, approximately 200 years ago. When homeopathic drugs first originated, people would typically consult with a licensed homeopathic practitioner, who would compound his or her own homeopathic remedy, or provide a prescription to the patient. Food and Drug Administration Compliance Policy Guide ("CPG") § 400.400.

20. Historically, homeopathic drugs were also not labeled and there was no direct-to-consumer advertising. Instead, homeopathic remedies were primarily marketed to licensed homeopathic practitioners. CPG § 400.400.

[1] *See* http://www.healthguidance.org/entry/12178/1/An-Introduction-to-Homeopathic-Remedies.html, last visited on May 9, 2012.

21. There was good reason for this historical practice: Homeopathic drugs are intended to be "'individualized' or tailored to each person-it is not uncommon for different people with the same condition to receive different treatments." nccam.nih.gov/sites/nccam.nih.gov/files/homeopathy.pdf. Defendants do not communicate this important fact to consumers regarding the Products.

22. Instead, Defendants market and sell one-size-fits-all, combination homeopathic remedies directly to consumers in the over-the-counter ("OTC") aisles of major retail stores. CPG § 400.400.

23. Most consumers who purchase homeopathic drugs in the OTC aisles of retail stores are unaware of homeopathic dilution principles, and are merely seeking a natural alternative to prescription or other OTC non-homeopathic (i.e., allopathic) drugs; and Defendants are aware of this reality. Ex. 2 (Oct. 1, 2007 Chain Drug Rev. article, stating: "Customers looking for homeopathic remedies in chain drug stores tend to be much different than the people who rely on natural food stores for these products, those in the industry note. 'Consequently,' points out Hyland's Inc. president Dale Nepsa, 'there's a vast difference between the way homeopathy is merchandised.' In the natural food store, he notes, shoppers tend to be better educated and have a rudimentary knowledge of homeopathy. . . . 'In a chain drug store,' Nepsa says, 'you don't have the same type of shopper or the same personnel. It's more of a self-service environment.'").

24. Indeed, Defendants take credit for being the first homeopathic drug company to break into the over-the-counter drug market in retail stores. Ex. 2 (June 21, 2004 Chain Drug Review article; and ALLEN0007121-7122 ["The trend of integrating 'natural' remedies with mainstream drugs on store shelves started in the early 1990s. A homeopathic brand called Hyland's, previously only sold in natural food stores, gets credit. It started by accident, said Hyland's CEO J.P. Borneman. A drugstore chain shelved Hyland's remedy for babies' teething pain with the rest of its

teething products. The product was selling well. 'We began to get the suspicion that a few products could hop the fence,' Borneman said. 'By 2000, we had a half-dozen products solidly in that class.'").

25. Defendants also strive to market the Products as natural, safe, and effective alternatives to prescription and non-homeopathic OTC drugs, and have taken steps to ensure that retailers will place them next to OTC allopathic remedies on store shelves. *See id.* But the latter category of drugs have undergone rigorous scrutiny by the FDA and its appointed scientific committees. *See, e.g.,* 21 C.F.R. § 330.10 (which only applies to OTC monographed drugs, and not Defendants' Products). In contrast, homeopathic drugs undergo no FDA review or approval of efficacy or labeling claims, an important fact to the purchasing decision that Defendants do not communicate to consumers, despite seeking to mimic OTC allopathic remedies in terms of package size, splashy graphics, and placement next to OTC allopathic drugs on store shelves.

26. Accordingly, a reasonable consumer is likely to believe that Defendants' Products are subject to review and approval just like the OTC allopathic products next to which they are shelved, which is untrue, and Defendants do not disclose anything to consumers to remedy this likely confusion. *See* labels.fda.gov/.

27. Indeed, the FDA, itself, has stated that it is aware of no scientific evidence that homeopathy is effective, another important fact that Defendants do not communicate to consumers. *See id.*

28. Defendant SHC uses its wholly owned subsidiary, Hyland's, exclusively for mass market, retail chain store homeopathic drug sales, aggressively striving to place Hyland's Products next to other manufacturers' OTC allopathic remedies, where Defendants can achieve far more lucrative profits. *See* Ex. 2 (June 21, 2004 Chain Drug Review article, confirming that "Hyland's Inc. has established itself as the brand most often found in chain drug stores across North America;" and "[o]ver the years, [Chief Executive Officer Jay Borneman] says, Hyland's has reinforced its position in

chain drug stores by increasing the number of SKUs it offers the trade class and by growing its market share in the channel. In fact, the company has a long heritage of doing business with drug chains. 'Hyland's Teething Tablets have been merchandised in chain drug stores since World War II,' he notes. '*We have aggressively marketed our products in chain drug stores for the past 12 years.*'"); *id.* ("The [Hyland's] line of approximately 200 medicines is tailored specifically for drug store customers, says Borneman. Hyland's corporate parent, Standard Homeopathic Co., manufactures more than 2,500 homeopathic medicines, but not all of them are applicable to mass market outlets.").

29. But Defendants know, and have known for many years, that consumers purchasing in these retail channels do not understand what homeopathy is, how it supposedly works, or the nature of the Products. *See, e.g.,* Ex. 2 (March 4, 2002 article in Chain Drug Review, quoting Dale Nepsa, Hyland's Vice President as stating, "'Young mothers and other consumers in chain drug outlets are different than shoppers in natural food stores,' . . . 'The chain drug channel is basically a self-sevice environment,' he observes, 'and consumers are generally not as conversant in the category.'"); Ex. 2 (June 21, 2004 Chain Drug Review article, quoting CEO Jay Borneman as stating, "'You don't need to know anything technical about homeopathy to use Hyland's products, . . .'"); Ex. 2 (Oct. 1, 2007 Chain Drug Review article, stating, "not all consumers know what they are buying when they purchase a homeopathic item. In most cases, they say, shoppers are attracted to an item's all-natural qualities before they are drawn to its homeopathic heritage. In many cases homeopathy is not even a factor in their decision to buy a product. 'A lot of people who are buying homeopathy in food, drug and mass don't know the products are homeopathic,' Hylands' Nepsa says.").

30. Defendants have also capitalized on the public's desire to purchase "natural" medicines, heavily branding every one of its Products with the words

"natural," "all natural," and/or "100% natural." Ex. 1; *see also* Ex. 2 (June 25, 2007 Chain Drug Rev. article, stating "Hyland's Inc., the nation's oldest manufacturer of homeopathic medicine, has seen tremendous growth in recent years, as more consumers look to natural medicines;" and "the company's success is grounded in providing consumers with unprecedented over-the-counter access to the natural alternatives they are seeking.").

31. Defendants have also emphasized the supposed natural characteristics of their Products by placing the words, "natural," "all natural," and/or "100% natural" on all of the Products in a green bar, banner, pull down, or leaf. *See* Ex. 1; *see also* Ex. 2 (July 21, 2004 Chain Drug Reg. article, quoting CEO Jay Borneman as stating, "We focus on consumers' need for natural medicines . . ."). But, as detailed further herein, not all of Defendants' Products are natural, and Defendants know or should know those Products are not natural and should not be advertised as such.

32. Defendants have pursued their false and deceptive marketing campaign with the fore knowledge that consumers are confused about the true nature of their Products. *See* Ex. 2 (Oct. 1, 2007 Chain Drug Review article, stating "not all consumers know what they are buying when they purchase a homeopathic item. . . . In many cases homeopathy is not even a factor in their decision to buy a product. 'A lot of people who are buying homeopathy in food, drug and mass don't know the products are homeopathic,' Hylands' Nepsa says.").

33. Defendants have also taken advantage of highly publicized problems with OTC and prescription allopathic medicines, such as harmful side effects of acetaminophen in cough/cold remedies and reports of addiction to sleep aid products. Ex. 2 (June 25, 2007 Chain Drug Rev., stating "In the wake of highly publicized side effects often caused by expensive prescription sleep aids, a growing number of families are turning to Hyland's Calms Forte, which promises 100%-natural relief of nervous tension and insomnia without side effects or the danger of addiction.").

34. "Today the homeopathic drug market has grown to become a multimillion dollar industry in the United States, with a significant increase shown in the importation and domestic marketing of homeopathic drug products." CPG § 400.400. "The homeopathic cough/cold/ flu medicine category, [homeopathic drug manufacturers] say, generates over $100 million a year in sales." Ex. 2 (Sept. 6, 2011 Chain Drug Review article).

35. Health care costs in the United States reached almost $2.6 trillion in 2010, with 10% of that amount spent on retail and prescription drugs. www.kaiseredu.org/issue-modules/us-health-care-costs/background-brief.aspx. But unless drug manufacturers disclose the complete truth to consumers, consumers are unable to make informed decisions about where to spend their limited healthcare dollars. *See id.*

36. Homeopathic drugs must comply with the minimal requirements set forth in the CPG. But, the FDA has cautioned that compliance with the CPG, "the HPUS, USP, or NF does not establish that [a homeopathic drug] has been shown by appropriate means to be safe, effective, and not misbranded for its intended use." CPG § 400.400.

37. On August 26, 2011, the non-profit group, Center for Public Inquiry, petitioned the FDA to require homeopathic drug manufacturers to undergo the same efficacy requirements as other OTC products, and to label their drugs with a disclaimer that states: "The FDA has not determined that this product is safe, effective, and not misbranded for its intended use." See *Gallucci v. Boiron, Inc.*, Case No. 3:11-CV-2039 JAH (S.D. Cal.), Dkt. No. 93-1 at p. 18.

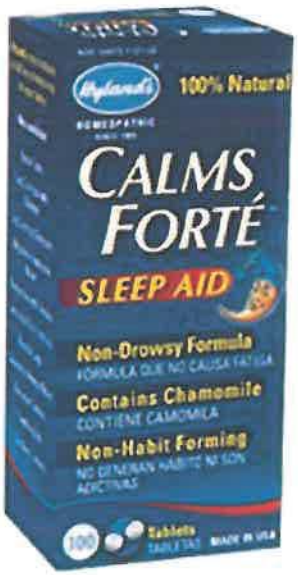
38. As a result of other class action litigation, such as *Gallucci*, *supra*, other homeopathic drug manufacturers have voluntarily agreed to implement a FDA disclaimer similar to the one noted above, along with additional injunctive relief, such as a dilution disclaimer and explanation of homeopathic dilution for consumers. *See,*

e.g., *Gallucci*, Dkt. No. 105 at pp. 13-15; Dkt. No. 125 at pp. 9-10. Thus, even those in the industry recognize a need to more truthfully label homeopathic drugs for the average consumer. *See id.*

39. At some point during the Class Period, and as a result of *Gallucci*, Defendants initiated a packaging change to its homeopathic products, labeling them with the vague and ambiguous phrase, "The [FDA] does not evaluate homeopathic products." This disclaimer does not achieve the same result as the *Gallucci* injunctive relief because it is not linked to any efficacy statements on the Products' packaging, and does not discuss dilution at all. Further, Defendants continue to market its Products with false or deceptive advertising claims that are not addressed by the disclaimer, as more fully described herein.

FACTS

A. Hyland's Calms Forté ("Calms Forté")[2]



[2] *See* Exhibit 1 ("Ex. 1") attached hereto for larger images of Calms Forté and other Products.

40. During the Class Period defined herein, in 2009 and 2011, Plaintiff Allen purchased Calms Forté 32-caplet packages from various stores in Sarasota, Florida, including Walgreen's and Publix Supermarket. Ms. Allen's individual purchases ranged from approximately $6.50 to $8.

41. Sometime during 2008 or 2009, and during the Class Period defined herein, Plaintiff Xenos purchased Calms Forté on at least one occasion from a Walgreens or Walmart located in Decatur Georgia, or online from her home in Georgia. Ms. Xenos' individual purchases were approximately $10.00.

42. During the Class Period defined herein, in 2009, Plaintiff Nigh purchased Calms Forté on at least one occasion from a RiteAid or Target located in Morgan Hill, California. Ms. Nigh's individual purchases were approximately $10.00.

43. During 2005 to 2007, Plaintiff Rodriguez purchased Calms Forté on at least one occasion online from her home located in Florida. Her individual purchases were approximately $10.00. Plaintiff first discovered Defendants' unlawful acts described herein in 2012-2013, when she learned that the Defendants' Product violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading. Plaintiff, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to her, throughout the Class Period defined herein. Plaintiff is not a nutritionist, drug expert, or scientist, but rather a lay consumer who did not have the specialized knowledge that Defendants had.

44. Defendants advertise Calms Forté as a treatment and cure for "simple nervous tension and occasional sleeplessness." Defendants claim Calms Forté is a "Sleep Aid," "For Restless or Wakeful Sleep from Exhaustion," "100% Natural," "All Natural," "For Stress, Nervousness or Nervous Headache," "For Drowsiness with Incomplete Sleep," "For Nervous Irritability," has "Biochemic Phosphates for

Enhancing Cellular Function," helps consumers "Wake up Rested & Refreshed," and "Relieves Stress to Help you Sleep." These messages are reinforced through the use of a graphic depicting a smiling yellow moon wearing a blue night cap.

45. Calms Forté is composed of nothing more than sugar pellets or tablets onto which minute quantities of water have been absorbed. The purported active ingredients in Calms Forté are: *Avena Sativa 1X Double Strength*, *Humulus Lupulus 1X Double Strength*, *Chamomilla 2X (Chamomile)*, *Passiflora 1X Triple Strength*, *Calcarea Phosphorica (purported cellular function enhancer)*, *Ferrum Phosphoricum*, *Kali Phosphoricum*, *Natrum Phosphoricum*, and *Magnesia Phosphoricum*. Calms Forté, at best, contains only trace amount of "active ingredients" and has no effect on sleeplessness.

46. In purchasing Calms Forté, Plaintiff Allen relied upon various representations, taken together and in context, Defendants made on the Product's label, taken together and in context, such as the name of the Product itself, that it is "100% natural" and/or "natural," and the statements that Calms Forté will relieve her and her minor daughter's sleeplessness due to stress.

47. Plaintiffs Xenos, Nigh, and Rodriguez purchased Calms Forté because they wanted a more natural alternative to traditional over-the-counter remedies for anxiety/stress. Plaintiffs relied upon various representations, taken together and in context, Defendants made on the Product's label, taken together and in context, such as the name of the Product itself, that it is "100% natural" and/or "natural," and that Calms Forté is effective in relieving symptoms related to sleeplessness or feelings of stress.

48. Calms Forte is, however, not "100% natural" because it contains magnesium stearate, a synthetic chemical, that is often used as a flow aid or tablet lubricant. In addition, Calms Forte contains biochemical phosphates that are synthetically derived or chemically reduced, such as Calcarea phosphorica, for which

the HPUS states "is contained in bones (80%), and extracted from them by dissolving in hydrochloric acid and precipitating with ammonium hydroxide." *See* Ex. 5.

49. Calms Forté did not work for Plaintiffs as advertised.

50. Absent the misstatements described herein, Plaintiffs would not have purchased Calms Forté.

51. To the detriment of Plaintiffs and similarly situated consumers, the substances listed as the "active ingredients" in Calms Forté, are not active in combating sleeplessness. Moreover, because of enormous dilutions used in its preparation, the "active ingredients" are not actually present in the Calms Forté preparations sold to the Plaintiffs and other consumers. *See* the Ingredient List, Dilution Chart, and Advertising Claims Charts attached hereto as Exhibit 3.

52. The ingredients used in Calms Forté provide no health benefit. Moreover, at the stupendously high dilutions used to prepare the product, they can have no effect of any kind in humans because the odds are astronomically high that even a single molecule derived from the original "extract" of the "active ingredients" could be present in the solution used to soak the tiny balls of lactose which constitute the product sold to consumers.[3]

53. Defendants know that there are, at best, traceable amounts of active ingredients present in Calms Forté and therefore must be aware that Calms Forté cannot relieve any symptoms for which Defendants advertise the Product.

54. Further, Calms Forte contains magnesium stearate, which is not natural.

[3] The final stage in the preparation of Calms Forté, as is the case for all homeopathic "medicines," is the infusion of what is essentially water onto the surface of tiny balls of sugar. This effectuates an additional "dilution" of the water, imposing another layer of uncertainty upon the indeterminate but undeniably vast dilution in Defendants' Products.

55. Calms Forté comes in 32, 50 and 100 caplet bottle sizes and the price depends on the package size, starting at approximately $7.50 per 32-caplet package. Hence, Defendants' unfair and deceptive practices have enriched them by tens of millions of dollars, at the expense of tens of thousands of Americans.

56. Plaintiffs seek justice for themselves and for similarly-situated consumers of Calms Forté by means of this action, among other things, to enjoin the ongoing deceptive practices described herein.

B. Hyland's Teething Tablets ("Teething Tablets")

57. During 2003-2004 and 2006-2007, Plaintiff Xenos purchased Teething Tablets on several occasions, from a co-op in Georgia, or online from her home in Georgia. Ms. Xenos' individual purchases were approximately $10.00.

58. During the Class Period defined herein, in 2009, Plaintiff Nigh purchased Teething Tablets from Target and Rite Aid stores in Morgan Hill, California.

59. In 1993, Plaintiff Allen purchased Teething Tablets from Walgreens and Publix Supermarket in Sarasota, Florida.

60. Plaintiffs Xenos and Allen first discovered Defendants' unlawful acts described herein in 2012-2013, when they learned that the Defendants' Product

violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading.

61. Plaintiffs Xenos and Allen, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to them, throughout the Class Period defined herein. Plaintiffs are not nutritionists, drug experts, or scientists, but rather lay consumers who did not have the specialized knowledge that Defendants had.

62. Defendants advertise Teething Tablets for the relief of symptoms associated with baby teething, such as "Relieve Pain and Irritability from Teething," "Simple Restlessness and Wakeful Irritability Due to the Cutting of Teeth," "Soft Tablets Dissolve Instantly," "100% Natural" and "Helps Reduce Redness and Inflammation of Gums."

63. The purportedly active ingredients Teething Tablets include *Calcarea Phosphorica* (6X HPUS), *Chamomilla Recutita* (Chamomile) (6X HPUS), *Coffee Cruda* (6X HPUS) and *Belladonna* (12X HPUS). However, as with Calms Forté, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

64. Plaintiffs Xenos, Nigh and Allen purchased Teething Tablets, because she wanted a more natural alternative to traditional over-the-counter remedies. In purchasing Teething Tablets, Plaintiffs relied upon various representations, taken together and in context, Defendants made on the Product's label, taken together and in context, such as the Product's name itself, and that Teething Tablets are effective in relieving symptoms associated with baby teething, such as, "Relieve Pain and Irritability from Teething," "100% natural," among other representations.

65. Teething Tablets are not, however, "100% natural," because they contain biochemical phosphates that are synthetically derived or chemically reduced. For

example, the Product contains Calcarea phosphorica, for which the HPUS states "is contained in bones (80%), and extracted from them by dissolving in hydrochloric acid and precipitating with ammonium hydroxide." *See* Ex. 5. Further, the children's products (Colic Tablets and Teething Tablets) contain an acacia gum made with isopropyl alcohol but isopropyl alcohol is not listed as an ingredient in these Products. SHCALLEN011730.

66. Teething Tablets did not work for Plaintiffs as advertised.

67. Absent the misstatements described herein, Plaintiffs would not have purchased Teething Tablets.

68. Plaintiffs seek justice for themselves and for similarly-situated consumers of Teething Tablets by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

C. Hyland's Migraine Headache Relief ("Migraine Headache Relief")

69. During the Class Period defined herein, in 2009, Plaintiff Xenos purchased Migraine Headache Relief on at least one occasion, from a co—op located in North Carolina, or online from her home in Georgia. Ms. Xenos' individual purchases were approximately $10.00.

70. During the Class Period defined herein, in 2009, Plaintiff Allen purchased Migraine Headache Relief on at least one occasion, from Walgreens and Publix Supermarket located in Sarasota, Florida. Ms. Allen's individual purchases were approximately $10.00.

71. During the Class Period defined herein, in 2011, Plaintiff Sisti purchased Migraine Headache Relief on at least one occasion, from a CVS store located in San Diego, California. Ms. Sisti's individual purchases were approximately $10.00.

72. During the Class Period defined herein, in 2009-2010, Plaintiff Rodriguez purchased Migraine Headache Relief on at least one occasion, from a Love's Whole Foods located in Florida. Ms. Rodriguez' individual purchases were approximately $10.00.

73. Defendants advertise Migraine Headache Relief as a natural remedy for migraines, that "works fast to relieve migraine headache pain without aspirin, caffeine or sedatives" and that the Product is "100% Natural," "Aspirin Free," "Quick Dissolving Tablets," "Relieves Pressure, Throbbing, Light + Noise Sensitivity" and "Temporarily Relieves the Symptoms of Migraine Pain." One of the Migraine Headache Relief's packaging depicts a happy, smiling woman.

74. Plaintiffs purchased Migraine Headache Relief, because they wanted a more natural alternative to traditional over-the-counter remedies. In purchasing Migraine Headache Relief, Plaintiffs relied upon various representations, taken together and in context, Defendants made on the label of the Products, such as the Product's name itself, "works fast to relieve migraine headache pain without aspirin, caffeine or sedatives," "temporarily relieves the symptoms of migraine pain," "relieves pressure, throbbing, light and noise sensitivity, "Migraine Headache Relief," and "100% Natural."

75. The purported active ingredients in this Product are: *Glonoinum* (12X HPUS), *Belladonna* (6X HPUS), *Gelsemium* (6X HPUS), *Nux Vomica* (6X HPUS),

Iris Versicolor (6X HPUS) and *Sanguinaria Canadensis* (6X HPUS). However, as with Calms Forté and Teething Tablets, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

76. A reasonable consumer is not likely to be aware that Glonoinum is another name for Nitroglyceride, and Plaintiffs were not aware of this fact at the time of purchase.

77. Nitroglyceride is not natural because it is a synthetic derived through chemical processing (generally, by mixing sulfuric acid with nitric acid, or through mixing similar, cheaper sulfur and nitrous ingredients).

78. Migraine Headache Relief did not work for Plaintiffs as advertised.

79. Absent the misstatements described herein, Plaintiffs would not have purchased Migraine Headache Relief.

80. Plaintiffs seeks justice for themselves and for similarly-situated consumers of Migraine Headache Relief by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

D. Hyland's ClearAc ("ClearAc")

81. In 2005, Plaintiff Xenos purchased ClearAc on at least one occasion, from a co-op located in North Carolina, or online from her home in Georgia. Ms. Xenos' individual purchases were approximately $10.00.

82. Plaintiff first discovered Defendants' unlawful acts described herein in 2012-2013, when she learned that the Defendants' Product violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading.

83. Plaintiff, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to her, throughout the Class Period defined herein. Plaintiff is not a nutritionist, drug expert, or scientist, but rather a lay consumer who did not have the specialized knowledge that Defendants had.

84. Defendants advertise ClearAc as an "All Natural" remedy for the management and symptomatic relief of symptoms of pimples, blackheads and blemishes associated with common acne (acne vulgaris).

85. Plaintiff Xenos purchased ClearAc, because she wanted a more natural alternative to traditional over-the-counter remedies. In purchasing ClearAc, Plaintiff Xenos relied upon various representations, taken together and in context, Defendants made on the Product's label, such as the Product's name itself, and: "Natural Treatment for Pimples, Acne, Blackheads, and Oily Skin," "Medicated Skin Cleanser," "Gentle on Skin No Harsh Chemicals," "Hyland's 100% Natural ClearAc Acne Tablets," and "No Messy Makeup," among other representations.

86. The purported active ingredients in this Product include *Echinacea Ang.* (6X HPUS), *Berberis Vulg.* (6X HPUS), *Sulphur Iod* (6X HPUS) and *Hepar Sulph* (6X HPUS). However, as with Calms Forté, Teething Tablets and Migraine Headache Relief, the active ingredients, even if they were otherwise effective, are so greatly

diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

87. ClearAc did not work for Plaintiff Xenos as advertised.

88. Absent the misstatements described herein, Plaintiff would not have purchased Hyland's ClearAc.

89. Plaintiff seeks justice for herself and for similarly-situated consumers of ClearAc by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

E. Hyland's Poison Ivy/Oak Tablets ("Poison Ivy/Oak Tablets")

90. In 2005, Plaintiff Xenos purchased Poison Ivy/Oak Tablets on at least one occasion, from a co-op located in North Carolina, or online from her home is Georgia. Ms. Xenos' individual purchases were approximately $10.00.

91. Plaintiff first discovered Defendants' unlawful acts described herein in 2012-2013, when she learned that the Defendants' Product violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading.

92. Plaintiff, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to her, throughout the Class Period defined herein. Plaintiff is not a nutritionist, drug expert, or scientist, but rather a lay consumer who did not have the specialized knowledge that Defendants had.

93. Defendants advertise Poison Ivy/Oak Tablets as "Natural Relief" for "Symptomatic Treatment after Contact with Poison Ivy or Oak," "100% Natural," and to relieve the symptoms such as skin break outs, itching, burning and blisters.

94. Plaintiff Xenos purchased Poison Ivy/Oak Tablets, because she wanted a more natural alternative to traditional over-the-counter remedies. In purchasing Poison Ivy/Oak Tablets, Plaintiff Xenos relied upon various representations, taken together and in context, Defendants made on the label and elsewhere, such as the Product's name itself, that the Product provides a "Natural Relief for Itching, Burning and Crusting Skin Due to Exposure to Poison Ivy or Oak".

95. The purported active ingredients in this Product include *Rhus Toxicodendron* (6X HPUS), *Croton Tiglium* (6X HPUS) and *Xerophyllum* (6X HPUS). However, as with Calms Forté, Teething Tablets, Migraine Headache Relief and ClearAc, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

96. Poison Ivy/Oak Tablets did not work for Plaintiff Xenos as advertised.

97. Absent the misstatements described herein, Plaintiff Xenos would not have purchased Poison Ivy/Oak Tablet.

98. Plaintiff seeks justice for herself and for similarly-situated consumers of Poison Ivy/Oak Tablets by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

F. Hyland's Colic Tablets ("Colic Tablets")

99. In 1993, Plaintiff Allen purchased Colic Tablets on at least one occasion, from Walgreens and Publix Supermarket located in Sarasota, Florida. Ms. Allen's individual purchases were approximately $10.00.

100. Plaintiff first discovered Defendants' unlawful acts described herein in 2012-2013, when she learned that the Defendants' Product violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading.

101. Plaintiff, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to her, throughout the Class Period defined herein. Plaintiff is not a nutritionist, drug expert, or scientist, but rather a lay consumer who did not have the specialized knowledge that Defendants had.

102. Defendants represent that Colic Tablets are "100% Natural," "Soft Tablets [that] Dissolve Instantly," "[without] Side Effects," that provide "Symptomatic Relief from Colic in Children;" and is "Effective" for Gas Pain and Irritability."

103. Plaintiff Allen purchased Colic Tablets, because she wanted a more natural alternative to traditional over-the-counter remedies. In purchasing the Product, Plaintiff Allen relied upon various representations Defendants made on the Product's label, taken together and in context, such as the Product's name itself, "Symptomatic Relief for Colic in Children," and "100% Natural."

104. The purported active ingredients in this Product include *Dioscorea* (3X HPUS), *Chamomilla* (3X HPUS) and *Colocynth* (3X HPUS). However, as with Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc and Poison Ivy/Oak Tablets, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses. Further, the children's products (Colic Tablets and Teething Tablets) contain an acacia gum made with isopropyl alcohol but isopropyl alcohol is not listed as an ingredient in these Products. SHCALLEN011730.

105. Colic Tablets did not work for Plaintiff as advertised.

106. Absent the misstatements described herein, Plaintiff would not have purchased Colic Tablets.

107. Plaintiff seeks justice for herself and for similarly-situated consumers of Colic Tablets by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

G. Hyland's Leg Cramps with Quinine

108. During the Class Period defined herein, in 2009, Plaintiff Allen purchased Leg Cramps with Quinine on at least one occasion, from a Walgreens and Publix Supermarket located in Sarasota, Florida. Ms. Allen's individual purchases were approximately $10.00.

109. Defendants represent that Leg Cramps with Quinine is a "non-habit forming" "100% natural," product to "relax calf & foot cramps," to "stop the pain!"

110. Plaintiff Allen purchased Leg Cramps with Quinine because she wanted a more natural alternative to traditional over-the-counter remedies and because she

believed that quinine was helpful for leg cramps. Allen Dep. Tr. At 57 (condensed version). In purchasing Leg Cramps with Quinine, Plaintiff Allen relied upon various representations, taken together and in context, Defendants made on the Product's label, such as the Product's name itself, "100% Natural," that it could be taken any time of day or night to alleviate lower leg cramps, had quinine in it, and "Temporarily relieves the symptoms of pain and cramps in lower body, legs, feet and toes," among other representations.

111. The purported active ingredients in this Product include *Calcarea Carbonica* (12X HPUS), *Causticum* (12X HPUS), *Chamomilla* (6X HPUS), *Cinchona Officinalis* (3X HPUS), *Cuprum Metallicum* (12X HPUS), *Lycopodium* (12X HPUS), *Magnesia Phosphorica* (6X HPUS), *Rhus Toxicodendron* (6X HPUS), *Silicea* (12X HPUS) and *Sulphur* (6X HPUS). However, as with Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets and Colic Tablets, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

112. Defendants also sell an identical Product called Leg Cramps with Quinine PM. The sole difference between Leg Cramps with Quinine and Leg Cramps with Quinine PM are the inclusion of the letters "PM" on the front of the package of the latter Product. Otherwise, the advertising claims and ingredients are identical. *See* Ex. 1.

113. Leg Cramps with Quinine does not state "not for nighttime use" or similar language to convey to consumers that the Product is not intended to be used for nighttime leg cramp relief. *See* Ex. 1.

114. The purported ingredient that adds quinine to Defendants' Leg Cramps products is cinchona bark. *See* Ex. 4 (FDA's warning letter to Defendants dated April 29, 2011).

115. But, the FDA has stated that "*Quinine . . . is not considered safe and effective for the treatment or prevention of leg cramps -- an 'off-label' (non-FDA-approved) use.*" fda.gov/ForHealthProfessionals/ArticlesofInterest/ucm317811.htm. Therefore, Defendants' Leg Cramps Products are all unlawfully labeled, are unapproved new drugs, and accordingly misbranded under the California Sherman Law. Cal. Health & Safety Code §§ 110100, 110105, 110110, 110111 (incorporating all food, drug, OTC drug, and good manufacturing practices of the federal Food, Drug and Cosmetic Act as the laws of this state).

116. Further, 21 C.F.R. § 310.546(a) states: "There is a lack of adequate data to establish general recognition of the safety and effectiveness of quinine sulfate, vitamin E, *or any other ingredients* for OTC use in the treatment and/or prevention of nocturnal leg muscle cramps." Accordingly, Defendants' Leg Cramps Products are unlawfully labeled, are unapproved new drugs, and accordingly misbranded under the California Sherman Law. *See id.*; *id.* § 310.546(b); Cal. Health & Safety Code §§ 110100, 110105, 110110, 110111.

117. In addition, on April 29, 2011, the FDA warned Defendants that their Leg Cramps Products were falsely and misleadingly labeled. *See* Ex. 4 ("The labeling of 'Leg Cramps with Quinine' and 'Leg Cramps PM with Quinine' prominently displays the ingredient 'Quinine'" on the front of the package and in the name of the product. The labeling is false and misleading because it suggests that quinine is the active ingredient when in fact the active ingredient is 'Cinchona Officinalis.' Further, the label identifies this active ingredient as 'Cinchona Officinalis 3X HPUS (Quinine).' According to the HPUS, although Cinchona bark contains quinine, it also contains other related alkaloids. Your selective identification of only one of the alkaloids in Cinchona bark is false and misleading because it incorrectly suggests that there is only one alkaloid in Cinchona bark.")

118. Further, Leg Cramps with Quinine contains causticum, also known as lime. The HPUS directs that "recently burnt lime" be used. Burning lime is a chemical alteration (calcination) and converts it into the highly caustic material known as quicklime (calcium oxide, CaO). The addition of water to quicklime converts it further to slaked lime (calcium hydroxide). Slaked lime is considered toxic by the National Institutes of Health. www.nlm.nih.gov/medlineplus/ency/article/002910.htm

119. The Product also contains potassium bisulfate, because the HPUS directs that the slaked lime be added, equal parts, to potassium bisulfate (the potassium salt of sulfuric acid), a food additive. *See* 21 C.F.R. § 182.3616 (designating potassium bisulfate as a "Chemical Preservative[]"). Potassium bisulfate—which makes us 50% of Causticum—is also artificially produced, typically by heating potassium sulfate with sulfuric acid.

120. This product contains Cuprum metallicum (i.e., copper). Too much copper can be toxic, www.nlm.nih.gov/medlineplus/ency/article/002419.htm, so even if this ingredient were natural, it is deceptive because consumers perceive the benefits of natural products as being wholesome and better for their health than synthetic, manmade or artificial products.

121. Leg Cramps with Quinine did not work for Plaintiff as advertised.

122. Absent the misstatements described herein, Plaintiff would not have purchased Leg Cramps with Quinine.

123. Plaintiff seeks justice for herself and for similarly-situated consumers of Hyland's Leg Cramps with Quinine, by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

H. Hyland's Leg Cramps ("Leg Cramps")

124. During the Class Period defined herein, in 2011, Plaintiff Smith purchased Leg Cramps on more than one occasion from a Henry's/Sprouts store located in Vista and Oceanside, California. Her purchases cost approximately $10 each.

125. During the Class Period defined herein, in 2008-2009, Plaintiff Xenos purchased Leg Cramps at least once from a Walmart or Walgreens located in Decatur, Georgia, or online. Her purchases cost approximately $10 each.

126. Even if the foregoing were not true, Plaintiff Xenos first discovered Defendants' unlawful acts described herein in 2012-2013, when she learned that the Defendants' Product violates the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations, and that the labels were untrue and/or misleading.

127. Plaintiff, in the exercise of reasonable diligence, could not have discovered earlier Defendants' unlawful acts described herein because the violations were known to Defendants, and not to her, throughout the Class Period defined herein.

Plaintiff is not a nutritionist, drug expert, or scientist, but rather a lay consumer who did not have the specialized knowledge that Defendants had.

128. Defendants represent, among other representations, that Leg Cramps "temporarily relieves the symptoms of cramps and pains in lower back and legs," is "100% natural," that it contains quinine, "relax[es] calf and foot cramps," and "stop[s] the pain!"

129. In purchasing Leg Cramps, Plaintiffs relied upon various representations, taken together and in context, Defendants made on the Product's label, such as the Product's name itself, that it is "100% natural," can be taken any time of day or night to alleviate lower leg cramps, has quinine, and is effective at relaxing calf and foot cramps.

130. The purported active ingredients in this Product include *Cinchona Officinalis* (3X HPUS), *Viscum Album* (3X HPUS), *Gnaphalium Polycephalum* (3X HPUS), *Rhus Toxicodendron* (6X HPUS), *Aconitum Napellus* (6X HPUS), *Ledum Pal* (6X HPUS) and *Magnesia Phosphorica* (6X HPUS).

131. However, as with Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets, Colic Tablets and Leg Cramps with Quinine, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

132. Defendants also sell identical Products called Leg Cramps with Quinine and Leg Cramps with Quinine PM. The sole difference between these Products are the words "with Quinine" on the front of the Leg Cramps with Quinine and "with Quinine PM" on Leg Cramps with Quinine PM packages. Otherwise, the advertising claims and ingredients are identical. *See* Ex. 1.

133. Leg Cramps does not state "not for nighttime use" or similar language to convey to consumers that the Product is not intended to be used for nighttime leg cramp relief. *See id.*

134. The purported ingredient that adds quinine to Defendants' Leg Cramps products is cinchona bark, which has some quinine but also has other alkaloids and which the FDA determined was false and misleading advertising. *See* Ex. 4_ (FDA's warning letter to Defendants dated April 29, 2011).

135. Further, the FDA has stated that "Quinine . . . is not considered safe and effective for the treatment or prevention of leg cramps -- an 'off-label' (non-FDA-approved) use." fda.gov/ForHealthProfessionals/ArticlesofInterest/ucm317811.htm. Therefore, Defendants' Leg Cramps Products are all unlawfully labeled, are unapproved new drugs, and accordingly misbranded under the California Sherman Law. Cal. Health & Safety Code §§ 110100, 110105, 110110, 110111 (incorporating all food, drug, OTC drug, and good manufacturing practices of the federal Food, Drug and Cosmetic Act as the laws of this state).

136. Further, 21 C.F.R. § 310.546(a) states: "There is a lack of adequate data to establish general recognition of the safety and effectiveness of quinine sulfate, vitamin E, or any other ingredients for OTC use in the treatment and/or prevention of nocturnal leg muscle cramps." Accordingly, Defendants' Leg Cramps Products are unlawfully labeled, are unapproved new drugs, and accordingly misbranded under the California Sherman Law. *See id.*; *id.* § 310.546(b); Cal. Health & Safety Code §§ 110100, 110105, 110110, 110111.

137. Further, Leg Cramps with Quinine contains non-natural ingredients, such as causticum, also known as lime. The HPUS directs that "recently burnt lime" be used. Burning lime is a chemical alteration (calcination) and converts it into the highly caustic material known as quicklime (calcium oxide, CaO). The addition of water to quicklime converts it further to slaked lime (calcium hydroxide). Slaked lime

is considered toxic by the National Institutes of Health. www.nlm.nih.gov/medlineplus/ency/article/002910.htm

138. The Product also contains potassium bisulfate, because the HPUS directs that the slaked lime be added, equal parts, to potassium bisulfate (the potassium salt of sulfuric acid), a food additive. *See* 21 C.F.R. § 182.3616 (designating potassium bisulfate as a "Chemical Preservative[]"). Potassium bisulfate—which makes us 50% of Causticum—is also artificially produced, typically by heating potassium sulfate with sulfuric acid.

139. This product contains Cuprum metallicum (i.e., copper). Too much copper can be toxic, www.nlm.nih.gov/medlineplus/ency/article/002419.htm, so even if this ingredient were natural, it is deceptive because consumers perceive the benefits of natural products as being wholesome and better for their health than synthetic, manmade or artificial products.

140. Leg Cramps did not work for Plaintiffs as advertised.

141. Absent the misstatements described herein, Plaintiffs would not have purchased Leg Cramps.

142. Plaintiffs seek justice for herself and for similarly-situated consumers of Leg Cramps, by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

I. Hyland's Defend Cold & Cough Night ("Defend Cold & Cough Night")

144. During the Class Period defined herein, in 2011 Plaintiff Sisti purchased Defend Cold & Cough Night from a CVS store located in San Diego, California. Her purchase of this Product cost her approximately $10.

145. During the Class Period defined herein, in 2009-2010 Plaintiff Rodriguez purchased Defend Cold & Cough Night from Love's Whole Foods located in Ormond Beach, Florida, or online from her home in Florida. Her purchase of this Product cost her approximately $10 for each purchase.

146. Defendants advertise that Defend Cold & Cough Night "Relie[ves] Sleeplessness, Congestion, Cough, Sore Throat, Sneezing," "Temporarily relieves the symptoms of the common cold," is "100% Natural" through a peel down graphic with green background; and is "Dye Free," "Alcohol Free," and "Sugar Free."

147. In purchasing Defend Cold & Cough Night, Plaintiffs relied upon various representations, taken together and in context, Defendants made on the Product's label

and elsewhere, such as the Product's name itself and that the Product is "Natural," "100% Natural," and relieves "Sleeplessness, Congestion, Cough, Sore Throat, Sneezing."

148. The purported active ingredients in this product include *Allium Cepa* (6X HPUS), *Coffea Cruda* (6X HPUS), *Chamomilla* (6X HPUS), *Hepar Sulph Calc* (12X HPUS), *Hydrastis* (6X HPUS), *Natrum Muriaticum* (6X HPUS), *Nux Vomica* (6X HPUS), *Phosphorus* (12X HPUS), *Pulsatilla* (6X HPUS) and *Sulphur* (12X HPUS). However, as with Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets, Colic Tablets, Leg Cramps with Quinine and Leg Cramps, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

149. This Product also contains sodium benzoate and citric acid.

150. But, sodium benzoate is not natural. 21 C.F.R. Sec. 184.1733(a) states that "sodium benzoate is the chemical benzoate of soda (C7H5NaO2), produced by the neutralization of benzoic acid with sodium bicarbonate, sodium carbonate, or sodium hydroxide. The salt is not found to occur naturally."

151. Further, as with most citric acid used in manufactured products, the citric acid used in this Product is not natural because it is derived through the application of a solvent mixture to the mold aspergillus niger. *See* 21 C.F.R. § 173.280 (noting that the solvent includes "a mixture of octyl alcohol meeting the requirements of 172.864 of this chapter, synthetic isoparaffinic petroleum hydrocarbons meeting the requirements of 172.882 of this chapter, and tridodecyl amine").

152. In addition, when sodium benzoate is combined with citric acid, as this Product does, it can form the dangerous carcinogen and teratogen, benzene.

153. Absent the misstatements described herein, Plaintiffs would not have purchased Defend Cold & Cough Night.

154. Plaintiffs seek justice for themselves and for similarly-situated consumers of Defend Cold & Cough Night by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

J. Hyland's Defend Cold & Cough ("Defend Cold & Cough")

156. During the Class Period defined herein, in 2011 Plaintiff Sisti purchased Defend Cold & Cough from a CVS store, located in San Diego, California. In purchasing this Product, Ms. Sisti spent approximately $10.

157. Defendants advertise Defend Cold & Cough as "Effective Relief of . . . nasal congestion, cough, sore throat [and] sneezing," that is "Dye Free," "Alcohol Free," "Sugar Free," "Non-Habit Forming," "100% Natural" with a peel down graphic and green background, and "Works with your Body's Natural Healing Process."

158. In purchasing Defend Cold & Cough, Plaintiff relied upon various representations, taken together and in context, Defendants made on the Product's label

and elsewhere, such as the Product's name itself, that it is "100% natural," and provides "effective relief" of "Nasal Congestion, Cough, Sore Throat and Sneezing."

159. The purported active ingredients in this Product include *Allium Cepa* (6X HPUS), *Hepar Sulph Calc* (12X HPUS), *Hydrastis* (6X HPUS), *Natrum Muriaticum* (6X HPUS), *Phosphorus* (12X HPUS), *Pulsatilla* (6X HPUS), *Sulphur* (12X HPUS).

160. However, as with Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets, Colic Tablets, Leg Cramps with Quinine, Leg Cramps and Defend Cold & Cough Night, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

161. This Product also contains sodium benzoate and citric acid.

162. But, sodium benzoate is not natural. 21 C.F.R. Sec. 184.1733(a) states that "sodium benzoate is the chemical benzoate of soda (C7H5NaO2), produced by the neutralization of benzoic acid with sodium bicarbonate, sodium carbonate, or sodium hydroxide. The salt is not found to occur naturally."

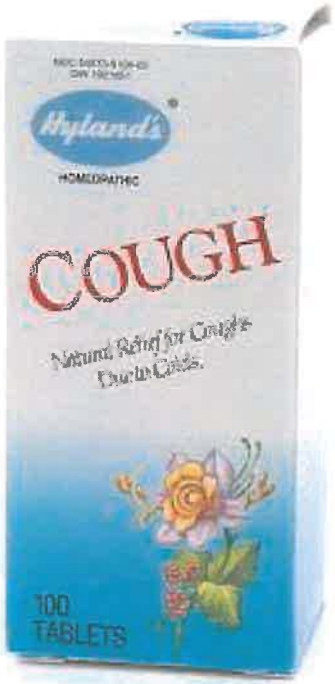
163. Further, as with most citric acid used in manufactured products, the citric acid used in this Product is not natural because it is derived through the application of a solvent mixture to the mold aspergillus niger. *See* 21 C.F.R. § 173.280 (noting that the solvent includes "a mixture of octyl alcohol meeting the requirements of 172.864 of this chapter, synthetic isoparaffinic petroleum hydrocarbons meeting the requirements of 172.882 of this chapter, and tridodecyl amine").

164. In addition, when sodium benzoate is combined with citric acid, as this Product does, it can form the dangerous carcinogen and teratogen, benzene.

165. Absent the misstatements described herein, Plaintiff would not have purchased Defend Cold & Cough.

166. Plaintiff seeks justice for herself and for similarly-situated consumers of Defend Cold & Cough by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

K. Hyland's Cough



167. During the Class Period defined herein, in 2011 Plaintiff Xu purchased Hyland's Cough from a Henry's/Sprouts store, located in Oceanside, California. His purchase cost him approximately $10.

168. Defendants advertise Hyland's Cough as a "natural relief for coughs due to colds" "especially coughs where assistance is raising mucous is necessary." Defendants also use a flower graphic, to emphasize the representation that the Product is "natural." On later versions of the packaging for this Product, Defendants again emphasized that the Product is "natural," "all natural," and/or "100% natural."

169. In purchasing Hyland's Cough, Plaintiff relied upon various representations, taken together and in context, Defendants made on the Product's label and elsewhere, such as the Product's name itself, that the Product is "natural," and relieves symptoms of cough due to the common cold.

170. The purported active ingredients in this Product include *Bryonia* (3X HPUS), *Causticum* (3X HPUS), *Hepar Sulph Calc.* (3X HPUS) and *Antimonium Tartaricum* (6X HPUS).

171. However, as with Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets, Colic Tablets, Leg Cramps with Quinine, Leg Cramps, Defend Cold & Cough Night and Defend Cold & Cough, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses. *See* Ex. 2, Dilution Chart, with regards to this Product.

172. This Product also contains sodium benzoate and citric acid.

173. But, sodium benzoate is not natural. 21 C.F.R. Sec. 184.1733(a) states that "sodium benzoate is the chemical benzoate of soda (C7H5NaO2), produced by the neutralization of benzoic acid with sodium bicarbonate, sodium carbonate, or sodium hydroxide. The salt is not found to occur naturally."

174. Further, as with most citric acid used in manufactured products, the citric acid used in this Product is not natural because it is derived through the application of a solvent mixture to the mold aspergillus niger. *See* 21 C.F.R. § 173.280 (noting that the solvent includes "a mixture of octyl alcohol meeting the requirements of 172.864 of this chapter, synthetic isoparaffinic petroleum hydrocarbons meeting the requirements of 172.882 of this chapter, and tridodecyl amine").

175. In addition, when sodium benzoate is combined with citric acid, as this Product does, it can form the dangerous carcinogen and teratogen, benzene.

176. Absent the misstatements described herein, Plaintiff would not have purchased Hyland's Cough.

177. Plaintiff seeks justice for himself and for similarly-situated consumers of Hyland's Cough by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

L. Hyland's Seasonal Allergy Relief ("Seasonal Allergy Relief")

178. During the Class Period defined herein, in early 2012, Plaintiff Xu purchased Seasonal Allergy Relief from a Henry's/Sprouts store, located in Oceanside, California. He spent approximately $10 to purchase this Product.

179. Defendants advertise Seasonal Allergy Relief as a "Non-Drowsy Formula" "For Indoor & Outdoor Allergies" that relieves "Itchy Watery Eyes," "Sneezing," "Runny Nose," and "Itchy Nose and Throat," is "100% Natural" and "Quick-Dissolving Tablets."

180. In purchasing Seasonal Allergy Relief, Plaintiff relied upon various representations, taken together and in context, Defendants made on the Product's label and elsewhere, such as the Product's name itself, "100% natural" with green leaves further implying ingredients from nature, and that the Product "temporarily relieves the symptoms of hay fever or other upper respiratory allergies from mold, animal dander, pollen, ragweed, and grasses."

181. The purported active ingredients in this Product include *Allium Cepa* (6X HPUS), *Natrum Muriaticum* (6X HPUS), *Histaminum Hydrochloricum* (12X HPUS), *Luffa Operculata* (12X HPUS), *Galphimia Glauca* (12X HPUS) and *Nux Vomica* (^X HPUS).

182. However, as with Calms Forté, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets, Colic Tablets, Leg Cramps with Quinine, Leg Cramps, Defend Cold & Cough Night, Defend Cold & Cough and Hyland's Cough, the active ingredients, even if they were otherwise effective, are so greatly diluted as to be effectively non-existent in the Product, such that the Product is ineffective for its intended uses.

183. Histaminum Hydrocholricum is not, however, natural, among other reasons, because it is a synthetic or artificial drug ingredient typically used in allopathic cold and cough medicines.

184. Absent the misstatements described herein, Plaintiff would not have purchased Seasonal Allergy Relief.

185. Plaintiff seeks justice for himself and for similarly-situated consumers of Seasonal Allergy Relief by means of this action, among other reasons, to enjoin the ongoing deceptive practices described herein.

ADDITIONAL ALLEGATIONS, MISREPRESENTATIONS AND OMISSIONS AS TO ALL PRODUCTS

186. Defendants' advertising of the Products are and have been the subject of an extensive, comprehensive, and uniform marketing campaign in various media through the United States, including the internet.

135. Defendants advertise, distribute and sell the Products in OTC aisles in major retail stores throughout California, and other states in the United States. All of the Products' packaging is uniform, no matter in which State in which it appears.

187. Defendants primarily advertise and promote the Products through the

labeling claims and images on the front of the Products' packages. Among other things, the Products' names clearly state what the ailments and symptoms the Products are designated for. Label descriptions on the Product packaging, taken as a whole, further clarify what each Product is supposed to do. As would any reasonable consumer, Plaintiffs and the Class relied on the Products' package claims in purchasing the Products.

188. Defendant' marketing and promotion of the Products was supported by false and misleading claims containing material omissions and misrepresentations, as detailed herein.

189. For example, Defendants represent that "Hyland's Homeopathic Medicines are manufactured according to the standards set forth in the Homeopathic Pharmacopoeia of the United States," but do not explain to consumers that homeopathy purportedly works by first aggravating symptoms according to the homeopathic principle of "like cures like."

190. Defendants also do not explain the homeopathic principle of dilutions to consumers, such as by informing consumers what the dilution levels of X, C, K on the Products' packaging means, in a language understandable to an average consumer.

191. In fact, because of the extreme dilutions of the purported "highest quality materials," Defendants' Products are nothing more than a placebo. Defendants' labeling and advertising claims are therefore false and deceptive because Hyland's Products are composed of nothing more than sugar pellets and/or tablets onto which minute quantities of water have been absorbed. The Products thus contain, at best, trace amounts of "active" ingredients, have no effect on ailments and symptoms they are advertised for, and in fact did not alleviate the ailments or symptoms for which Plaintiffs purchased them.

192. Further, on information and belief, each of the Products were first marketed to the public before all of the ingredients contained within them were

approved for listing in the Homeopathic Pharmacopeia of the United States ("HPUS"), the official drug compendium for homeopathic drugs in the United States. *See* Ex. 5 (pages from the HPUS for each ingredient, by Product, including the "First Approved" date listed therein). By containing even one non-HPUS ingredient, the Products are not official homeopathic drugs, CPG § 400.400, but are unapproved new drugs and are accordingly misbranded under the California Sherman Law. *See, e.g.*, Cal. Health & Safety Code §§ 110100, 110110, 110111.

193. Defendants are free to label Indications of Use, meaning what the Products are "effective" for, without any regulatory oversight, a material fact that is not disclosed to consumers.

194. Defendants are required to observe Good Manufacturing Practices (GMPs) under section 501(a)(2)(B) of the federal Food, Drug and Cosmetic Act, and its implementing regulation located at 21 C.F.R. § 211. This standard is mirrored under the California Sherman Law. Cal. Health & Safety Code § 110105. Defendants' manufacturing practices, however, are and have been substantially inadequate, far less than as represented to the public, including Plaintiffs and the Class. For example, the FDA has engaged in multiple investigations of Defendants' manufacturing facility, finding that Defendants performed inadequate verification of mixing times and other problems with verifying the ingredients in the Products, and maintaining GMPs. *See, e.g.,* Ex. 4. Not only was this conduct unlawful, but Defendants' violation of the GMPs are material information that was not communicated to the Plaintiffs and the Class. Instead, Defendants assert to the public a uniform marketing message that the produce pure, natural, and quality drugs that are effective for the remedies intended. The FDA investigations, however, reveal that the contrary is true; and that, homeopathic dilution aside, there are no, or are inconsistent levels of, the active ingredients in the Products. Defendants' failure to abide by GMPs also means that the Products are not official homeopathic drugs, according to the

HPUS' own standards, guidelines and/or requirements. Further, the children's products (Colic Tablets and Teething Tablets) contain an acacia gum made with isopropyl alcohol but isopropyl alcohol is not listed as an ingredient in these Products. SHCALLEN011730.

195. When purchasing the Products, Plaintiffs and the Class were seeking remedies that would provide the benefits, efficacy, and characteristics that Defendant marketed, promised, represented and warranted.

196. Plaintiffs and the Class purchased the Products believing they had the qualities they sought, based on the Products' deceptive or false labeling, but the Products were actually unacceptable to them as they did not possess the benefits, endorsements, proof, and characteristics as advertised.

197. Moreover, like all reasonable consumers and members of the class, Plaintiffs consider a label's compliance with law a material factor in their purchasing decisions. Plaintiffs are generally aware that the government carefully regulates OTC products and therefore have come to trust that information conveyed on packaged OTC product labels is truthful, accurate, complete, and fully in accordance and compliance with the law. As a result, Plaintiffs trust they can compare competing products on the basis of their labeling claims, to make a purchasing decision.

198. Like all reasonable consumers and members of the Class, Plaintiffs would not purchase an OTC product they knew was misbranded under law, *see, e.g.*, 21 U.S.C. § 352, which the federal government prohibits selling, *id.* § 331, and which carries with its sale criminal penalties, *id.* § 333. *See also* Cal. Health & Safety Code §§ 110100, 110105, 110110, 110111. Plaintiffs could not trust that the labels of Products misbranded under law are truthful, accurate and complete.

199. Similarly, like all reasonable consumers and members of the class, Plaintiffs would not purchase an OTC product they knew was an illegally marketed new drug for which the FDA has not determined its safety and efficacy.

200. In light of the foregoing, reasonable consumers, including Plaintiffs and other members of the class, were and are likely to be deceived by Defendants' advertising and marketing practices as detailed herein.

201. Further, Plaintiffs and other members of the Class purchased the Products instead of competing products based on the false statements, misrepresentations and omissions described herein.

202. Instead of receiving Products that had the benefits, advantages, endorsements, proof, and characteristics as advertised, Plaintiffs and other members of the Class received Products worth much less, or which were worthless, since the Products did not possess the characteristics, benefits, and qualities as advertised by Defendant.

203. At all times relevant herein, Defendant had a duty to disclose additional information to purchasing consumers, to correct all misunderstandings its omissions and misrepresentations created in the minds of those consumers.

204. Absent the misrepresentations and omissions described herein, which were and are material to an average consumer, Plaintiffs and other consumers would not have paid what they did for the Products.

205. Plaintiffs and the Class lost money as a result of Defendants' deception in that Plaintiffs and the Class did not receive what they had paid for.

206. Plaintiffs and the Class altered their position to their detriment and suffered damages in an amount equal to the amount they paid for the Products over the class period.

CLASS ACTION ALLEGATIONS

A. The Nationwide Consumer Class

207. Pursuant to Rules 23(a), (b)(3) and/or (b)(2) of the Federal Rules of Civil Procedure, Plaintiffs bring this action on behalf of themselves and a nationwide consumer class (hereinafter referred to as the "Class") initially defined as follows::

- All purchasers of Hyland's, Inc. and Standard Homeopathic Company's homeopathic Products entitled Calms Forte, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets, Colic Tablets, Leg Cramps with Quinine, Leg Cramps, Defend Cold & Cough Night, Defend Cold & Cough, Hyland's Cough and Seasonal Allergy Relief for personal or household use and not for resale, in the United States from period February 9, 2008 to the present (the "Class Period"). Excluded from the nationwide consumer class are governmental entities, Defendants, any entity in which Defendants have a controlling interest, their employees, officers, directors, legal representatives, heirs, successors and wholly or partly owned subsidiaries or affiliated companies, class counsel and their employees; and the judicial officers and their immediate family members and associated court staff assigned to this case.

208. The proposed Class is so numerous that individual joinder of all its members is impracticable. Due to the nature of the trade and commerce involved, however, Plaintiffs believe the total number of Class members is at least in the tends of thousands and members of the Class are numerous and geographically dispersed across the United States. While the exact number and identities of the Class members are unknown at this time, such information can be ascertained through appropriate investigation and discovery. The disposition of the claims of the Class members in a single class action will provide substantial benefits to all parties and to the Court.

209. Pursuant to Rule 23(b)(2), Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making final injunctive relief or corresponding declaratory relief and damages as to Calms Forte, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak Tablets, Colic Tablets, Leg Cramps with Quinine, Leg Cramps, Defend Cold & Cough Night, Defend Cold & Cough, Hyland's Cough and Seasonal Allergy Relief, appropriate with respect to the Class as a whole. In particular, Defendants have failed to disclose the true nature of the Products being marketed, as described herein.

210. There is a well-defined community of interest in the questions of law and fact involved affecting the Plaintiffs and the Class and these common questions of fact and law include, but are not limited to, the following:

a. Whether the claims discussed above are true, misleading, or reasonably likely to deceive;

b. Whether Defendants' alleged conduct violates public policy;

c. Whether the alleged conduct constitutes violations of the laws asserted herein;

d. Whether Defendants engaged in false or misleading advertising;

e. Whether Plaintiffs and Class members have sustained monetary loss and the proper measure of that loss;

f. Whether Plaintiffs and Class members are entitled to an award of punitive damages; and;

g. Whether Plaintiffs and Class members are entitled to declaratory and injunctive relief.

211. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class have been similarly affected by Defendants' common course of conduct since they all relied on Defendants' representations

concerning the homeopathic Products and purchased the Products based on those representations.

212. Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained counsel with substantial experience in handling complex class action litigation in general and scientific claims, including for homeopathic drugs, in particular. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the Class and have the financial resources to do so.

213. Plaintiffs and the members of the Class suffered, and will continue to suffer harm as a result of the Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the present controversy. Individual joinder of all members of the Class impracticable. Even if individual Class members had the resources to pursue individual litigation, it would be unduly burdensome to the courts in which the individual litigation would proceed. Individual litigation magnifies the delay and expense to all parties in the court system of resolving the controversies engendered by Defendants' common course of conduct. The class action device allows a single court to provide the benefits of unitary adjudication, judicial economy, and the fair and efficient handling of all Class members' claims in a single forum. The conduct of this action as a class action conserves the resources of the parties and of the judicial system and protects the rights of the class members. Furthermore, for many, if not most, a class action is the only feasible mechanism that allows an opportunity for legal redress and justice.

214. Adjudication of individual Class members' claims with respect to Defendants would, as a practical matter, be dispositive of the interests of other members not parties to the adjudication, and could substantially impair or impede the ability of other class members to protect their interests.

B. Alternate State Law Classes

215. In the event that the Court does not apply California law on a nationwide basis, Plaintiffs allege a separate class for the following states based on the applicable laws set forth in the alternate state law claims. Each class is defined as follows for the claims asserted under a particular jurisdiction's laws:

- All purchasers of Defendants' Products who reside in California and who purchased any of Defendants' Products for personal or household use and not for resale at any time on or after February 9, 2008, through and including the present (the "California Class").
- All purchasers of Defendants' Products who reside in Florida and who purchased any of Defendants' Products for personal or household use and not for resale at any time on or after February 9, 2008, through and including the present (the "Florida Class").
- All purchasers of Defendants' Products who reside in Georgia and who purchased any of Defendants' Products for personal or household use and not for resale at any time on or after February 9, 2008, through and including the present (the "Georgia Class").

FIRST CAUSE OF ACTION

VIOLATION OF CALIFORNIA'S CONSUMERS LEGAL REMEDIES ACT

California Civil Code §§ 1750, et seq.

(By Plaintiffs and on Behalf of the Class as Against All Defendants)

216. Plaintiffs repeat, reallege and incorporate by reference each and every allegation contained above as if fully set forth herein.

217. This cause of action is brought pursuant to the Consumers Legal Remedies Act, California Civil Code § 1750, *et seq*. (the "Act"). Plaintiffs and the members of the Class are consumers as defined by California Civil Code § 1761(d). The Products are goods within the meaning of the Act.

218. Defendants violated and continue to violate the Act by engaging in the following practices proscribed by California Civil Code §1770(a) in transactions with Plaintiffs and the Class which were intended to result in, and did result in, the sale of the Products:

> Representing that [the Products have] … characteristics … uses [or] benefits … which [they do] not have … (Civ. Code, § 1770, subd. (a) (5).)
>
> Representing that [the Product] is of a particular standard, quality or grade… if it is of another. (Civ. Code, § 1770, subd. (a) (7).)
>
> Advertising a good… with intent not to sell it as advertised. (Civ. Code, § 1770, subd. (a) (9).)
>
> Representing that [the Product has] been supplied in accordance with a previous representation when [it has] not. (Civ. Code, § 1770, subd. (a) (16).)

219. Defendants' violated the Act by representing through advertising of the Products as described above, when they knew, or should have known, that the representations and advertisements were false or misleading.

220. Plaintiffs and members of the Class reasonably relied upon the Defendants' representations as to the quality and attributes of their Products.

221. Plaintiffs and other members of the Class were deceived by Defendants' representations about the quality, characteristics and attributes of their Products, including but not limited to the purported benefits of their Products as expressed on each Product's packaging, taken as a whole, and that the Products are effective; "100% natural," "all natural," "natural" or any other implied or express claim that conveys the same marketing message; and that the Products were lawful. Plaintiffs and other Class members would not have purchased the Products had they known the Defendants' claims were untrue, and had they known the true nature of the Products.

222. Pursuant to section 1782 *et seq*. of the Act, Plaintiffs notified Defendants in writing by certified mail of the particular violations of § 1770 of the Act as to the

Products and demanded that Defendants rectify the problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act. Defendants' wrongful business practices regarding these Products constituted, and constitute, a continuing course of conduct in violation of the California's Consumers Legal Remedies Act since Defendants are still representing that these Products have characteristics, uses, benefits, and abilities which are false and misleading, and have injured Plaintiffs and the Class. Copies of Plaintiffs' CLRA letters are attached as Ex. 6 hereto.

223. Pursuant to California Civil Code § 1780(a), Plaintiffs and the Class seek an order of this Court enjoining Defendants from continuing to engage in unlawful, unfair, or deceptive business practices and any other act prohibited by law, and awarding Plaintiffs and the Class restitution and disgorgement, and awarding Plaintiffs and the Class damages and punitive damages.

224. Pursuant to California Civil Code § 1782(d), Plaintiffs and the Class seek a Court order enjoining the above-described wrongful acts and practices of the Defendants with respect to all of the Products.

SECOND CAUSE OF ACTION

VIOLATION OF THE UNFAIR COMPETITION LAW

California Business and Professions Code §§ 17200, et seq.

(By Plaintiffs and on Behalf of the Class as Against All Defendants)

225. Plaintiffs repeat, reallege and incorporate by reference each and every allegation contained above as if fully set forth herein.

226. California's Unfair Competition Law, Business and Professions Code § 17200 (the "UCL") prohibits any "unfair, deceptive, untrue or misleading advertising." For the reasons discussed above, Defendants have engaged in unfair, deceptive, untrue and misleading advertising in violation of the UCL.

227. The UCL also prohibits any "unlawful... business act or practice." Defendants have violated the UCL's prohibition against engaging in unlawful acts and practices by, *inter alia*, making the representations and omissions of material facts, as set forth more fully herein, and by violating among others, California Civil Code §§ 1572, 1573, 1709, 1710, 1711, 1770; California Health and Safety Code §§ 109875, *et seq*. ("California Sherman Law"), in particular, §§ 110100, 110105, 110110, 110111; Cal. Bus. & Prof. Code §§ 12601, *et seq*. ("Fair Packaging and Labeling Act"); *id.* § 17500 (False Advertising Law); California Commercial Code § 2313(1), and the common law. Such conduct is ongoing and continues to this date.

228. Plaintiffs and the Class reserve the right to allege other violations of law which constitute other unlawful business acts or practices.

229. California Business and Professions Code § 17200 also prohibits any "unfair"... business act or practice."

230. Defendants' acts, omissions, misrepresentations, practices and nondisclosures as alleged herein also constitute "unfair" business acts and practices within the meaning of the UCL in that its conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous as the gravity of the conduct outweighs any alleged benefits attributable to such conduct. Such conduct is ongoing and continues to this date.

231. Plaintiffs allege violations of consumer protection, unfair competition and truth in advertising laws in California and other states resulting in harm to consumers. Plaintiffs assert violation of the public policy of engaging in false and misleading advertising, unfair competition and deceptive conduct towards consumers. This conduct constitutes violations of the unfair prong of the UCL. Such conduct is ongoing and continues to this date.

232. There were reasonably available alternatives to further Defendants' legitimate business interests, other than the conduct described herein.

233. The UCL also prohibits any "fraudulent business act or practice."

234. Defendants' claims, nondisclosures (i.e., omissions), and misleading statements, as more fully set forth above, were false, misleading and/or likely to deceive the consuming public within the meaning of the UCL. Such conduct is ongoing and continues to this date.

235. Defendants' conduct caused and continues to cause substantial injury to Plaintiffs and the other members of the Class. Plaintiffs have suffered injury in fact as a result of Defendants' unfair conduct.

236. Defendants have thus engaged in unlawful, unfair and fraudulent business acts and practices and false advertising, entitling Plaintiffs to injunctive relief against Defendants, as set forth in the Prayer for Relief.

237. Pursuant to Business and Professions Code § 17203, Plaintiffs seek an order requiring Defendants to immediately cease such acts of unlawful, unfair and fraudulent business practices and requiring Defendants to engage in a corrective advertising campaign.

238. Plaintiffs also seek an order for the disgorgement and restitution of all monies from the sale of the Products, which were unjustly acquired through acts of unlawful, unfair, and/or fraudulent competition.

THIRD CAUSE OF ACTION

VIOLATION OF THE FALSE ADVERTISING LAW

California Business and Professions Code §§ 17500, et seq.

(By Plaintiffs and on Behalf of the Class as Against All Defendants)

239. Plaintiffs repeat, reallege and incorporate by reference each and every allegation contained above as if fully set forth herein.

240. Plaintiffs have standing to pursue this claim as Plaintiffs have suffered injury in fact as a result of Defendants' actions as set forth herein. Specifically, prior to the filing of this action, Plaintiffs purchased the Products in reliance upon

Defendants' marketing claims. Plaintiffs used the Products as directed, but the Products have not worked as advertised, nor provided any of the promised benefits.

241. Defendants' business practices as alleged herein constitute unfair, deceptive, untrue, and misleading advertising pursuant to California Business and Professions Code §§ 17500, *et seq*. because Defendants have advertised their Products in a manner that is untrue or misleading, or that is known to Defendants to be untrue or misleading.

242. Defendants' wrongful business practices have caused injury to Plaintiffs and the Class.

243. Pursuant to section 17535 of the California Business and Professions Code, Plaintiffs and the Class seek an order of this court enjoining Defendants from continuing to engage in deceptive business practices, false advertising, and any other act prohibited by law, including those set forth in the complaint.

244. Plaintiffs also seek an order for the disgorgement and restitution of all monies from the sale of Defendants' Products, which were unjustly acquired through acts of unlawful, unfair, deceptive and/or fraudulent competition.

FOURTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(On Behalf of Plaintiffs and all Class Members, as Against All Defendants)

245. Plaintiffs repeat, reallege and incorporate by reference each and every allegation contained above as if fully set forth herein.

246. On the Products' labels and through their marketing campaign as described above, Defendants made affirmations of fact or promises, or description of goods, which formed "part of the basis of the bargain" at the time of purchase.

247. Defendants' affirmations of fact or promises, or description of goods, that formed part of the basis of the bargain at the time of purchase are listed in the

Challenged Advertising Claims Chart, attached hereto as Exhibit 3, pages 38-39. *See also* Ex. 1 (pictures of the Products' containers and labels).

248. The warranties were breached because the Products did not live up to their warranties, as discussed in detail herein, and that breach caused injury in the form of the lost purchase price for the Products. *See, e.g.,* Cal. Com. Code § 2313(1); Fla. Stat. § 672.313; Ga. Stat. 11-2-313; *see also Zwart v. Hewlett-Packard Co.*, 2011 WL 3740805 (N.D. Cal., Aug. 23, 2011) (holding that online assertions can create warranties).

249. As a result of Defendants' breach of their warranties, Plaintiffs and the Class have been damaged in the amount of the purchase price of the Products they purchased.

FIFTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(On Behalf of Plaintiffs and the Class, as Against All Defendants)

250. Plaintiffs repeat, reallege and incorporate by reference each and every allegation contained above as if fully set forth herein.

251. Defendants, through their acts and omissions as set forth herein, in their sale, marketing and promotion of the Products, made representations to Plaintiffs and the Class that the Products provide the claimed health benefits, among other representations.

252. Plaintiffs and the Class bought the Products manufactured, advertised and sold by Defendants.

253. Defendants are merchants with respect to the goods of this kind which were sold to Plaintiffs and the Class, and there was in the sale to Plaintiffs and other members of the Class an implied warranty that those goods were merchantable, meaning that the Products had to conform to the promises or affirmations of fact made on the container or label and must have been fit for the ordinary purposes for which

the Products are used. Defendants' affirmations of fact or promises, or description of goods, that formed part of the basis of the bargain at the time of purchase are listed in the Challenged Advertising Claims Chart, attached hereto as Exhibit 3, pages 38-39. *See also* Ex. 1 (pictures of the Products' containers and labels).

254. However, Defendants breached that warranty implied in the sale of goods in that the Products did not conform to the promises or affirmations of fact made on their containers or labels, and were not fit for the ordinary purposes for which the Products are used, as set forth in detail herein.

255. As a result of Defendants' conduct, Plaintiffs and the Class did not receive goods as impliedly warranted by Defendants to be merchantable in that they did not conform to the promises and affirmations made on the container or label of the goods, and were not fit for the ordinary purposes for which the Products would be used.

256. Plaintiffs and Class have sustained damages as a proximate result of the foregoing breach of implied warranty in an amount to be determined at trial.

SIXTH CAUSE OF ACTION

VIOLATION OF THE MAGNUSSON-MOSS ACT,

15 U.S.C. §§ 2301, *et. seq.*;

(On Behalf of Plaintiffs and the Class, as Against All Defendants)

257. Plaintiffs repeat, reallege and incorporate by reference each and every allegation contained above as if fully set forth herein.

258. Plaintiffs bring this claim individually and on behalf of the members of the Class.

259. Plaintiffs make claims under state express and implied warranty law, as allowed under Section 2310(d)(1)(B) of the MMWA. With respect to those state claims, Defendants warranties are as alleged in Exhibit 3, pages 38-49, the Challenged Advertising Claims Chart. With respect to the remaining elements of common law

express and implied warranty, Plaintiffs incorporate by reference each and every allegation contained in their Fourth and Fifth Causes of Action as though fully set forth herein.

260. In addition, Defendants' Products are consumer products as defined in 15 U.S.C. § 2301(1).

261. Plaintiffs and Class members are consumers as defined in 15 U.S.C. § 2301(3).

262. Defendants are suppliers and warrantors as defined in 15 U.S.C. §§ 2301(4) and (5).

263. In connection with the sale of the Products, Defendants issued written warranties as defined in 15 U.S.C. § 2301(6) ("any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship is defect free or will meet a specified level of performance over a specified period of time, . . . which written affirmation, [or] promise, . . . becomes part of the basis of the bargain"), as follows:

a. Calms Forte: "Sleep Aid" (in Spanish - "Medicamiento Para El Sueño"), "Relieves Stress to Help You Sleep" (in Spanish – "Alivia el estres para ayudara conciliar el sueno"), "Homeopathic," "For Restless or Wakeful Sleep from Exhaustion," "For Stress, Nervousness or Nervous Headache," "For Drowsiness with Incomplete Sleep," "For Nervous Irritability," and "Biochemic Phosphates for Enhancing Cellular Function"

b. Teething Tablets: "Teething Tablets" (same in Spanish), "Relieves Pain and Irritability from Teething" (same in Spanish), "Homeopathic," "Temporarily Relieves the Symptoms of Simple Restlessness and

Wakeful Irritability Due to Cutting Teeth" and "Helps Reduce Redness and Inflammation of Gums"

c. Migraine Headache Relief: "Migraine Headache Relief" (same in Spanish), "Relieves Pressure, Throbbing, Light + Noise Sensitivity" (same in Spanish), "Homeopathic" and "Temporarily Relieves the Symptoms of Migraine Pain"

d. ClearAc: "Acne Tablets," "Indicated for the management and symptomatic relief of symptoms of pimples, blackheads and blemishes associated with common acne (acne vulgaris)," "Medicated Skin Cleanser," "Helps Clear Up Pimples, Acne, Blackheads, and Oily Skin," "No … Harsh Chemicals," "Homeopathic" and "The homeopathic medicines in ClearAc Tablets ..."

e. Poison Ivy/Oak Tablets: "Natural Relief for Itching, Burning and Crusting Skin Due to Exposure to Poison Ivy or Oak," "Relief of symptoms after contact with poison ivy or oak," "Safe for adults and children," "A homeopathic combination for Symptomatic Treatment after Contact with Poison Ivy or Oak," "Homeopathic"

f. Colic Tablets: "Colic Tablets," "Homeopathic," "Relieves Colic Gas Pain and Irritability" (same in Spanish), "Symptomatic Relief for Colic in Children," "No Side Effects"

g. Leg Cramps with Quinine: "Leg Cramps with Quinine" (same in Spanish), "Stop the Pain!" (same in Spanish), "Relief for Cramps and Pains in Lower Back and Legs" (same in Spanish), "Safe Pain Relief," "Temporarily Relieves the Symptoms of Cramps and Pains in Lower Back and Legs," "Relax Calf & Foot Cramps," "For the Temporary Symptomatic Relief of Cramps and Pains in Legs and Calves, Sciatica, Leg Cramp Pain, Joint Stiffness, Cramps and Pain in Lower Back,"

"Homeopathic," "Use Hyland's Leg Cramps if you have: leg cramp pain, pain in limbs & joints, cramps and pain in lower back, sciatica, cramps in calves & feet, pain and cramps in legs & calves, joint stiffness," "Hyland's Leg Cramps is a traditional homeopathic formula for the relief of symptoms of cramps and pains in lower back and legs often made worse by damp weather," "Working without contraindications or side effects," "Hyland's Leg Cramps is safe for adults and can be used in conjunction with other medications," and "Hyland's Leg Cramps stimulates your body's natural healing response to relieve symptoms"

h. Leg Cramps: "Leg Cramps," "Relax Calf & Foot Cramps," "[Contains] Quinine," "Temporarily relieves the symptoms of cramps and pains in lower back and legs," "Homeopathic"

i. Defend Cold & Cough Night: "Safe and Effective Relief of: Sleeplessness, Congestion, Cough, Sore Throat, Sneezing," "Temporarily relieves the symptoms of the common cold," "No known drug interactions," "Homeopathic," "HPUS indicates the active ingredients are in the official Homeopathic Pharmacopeia of the United States"

j. Defend Cold & Cough: "Safe and Effective Relief of Nasal Congestion, Cough, Sore Throat, Sneezing," "No Known Drug Interactions," "Homeopathic," "HPUS indicates the active ingredients are in the official Homeopathic Pharmacopeia of the United States"

k. Hyland's Cough: "Relief for Coughs Due to Colds," "Relief of symptoms of cough due to common cold, especially coughs where assistance is raising mucous is necessary," "A traditional homeopathic formula for the relief of symptoms of cough due to colds," "Working without contraindications or side effects," "Safe for adults and children,"

"Homeopathic," "HPUS," "HPUS indicates the active ingredients are in the official Homeopathic Pharmacopeia of the United States"

l. Seasonal Allergy Relief: "Seasonal Allergy Relief," "For Indoor & Outdoor Allergies" (same in Spanish), "Temporarily relieves the symptoms of hay fever or other upper respiratory allergies from mold, animal dander, pollen, ragweed, and grassed," "Homeopathic," "HPUS"

264. Defendants breached the above-noted warranties because the nature of the material in the Products was either defective or did not meet their specified level of performance over the specified period of time, as detailed herein.

265. By breaching the express written warranties stating that the Products relieve ailments and symptoms, Defendants have violated the statutory rights of Plaintiffs and Class members pursuant to the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301 et seq., thereby damaging Plaintiffs and Class members.

266. Plaintiffs notified the Defendants in writing of their claims and that the Plaintiffs were acting on behalf of a Class. *See* Ex. 6

SEVENTH CAUSE OF ACTION

VIOLATION OF FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT,

Fla. Stat. Ann § 501 201 *et seq.*

(On Behalf of Plaintiffs Allen and Rodriquez and the Florida Class, as Against All Defendants)

267. Plaintiffs Allen and Rodriguez repeat, re-allege and incorporate by reference each and every allegation contained above as if fully set forth herein.

268. This cause of action is brought pursuant to the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201 *et seq.* ("FDUTPA"). The purpose of FDUPTA is to "protect the consuming public…from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade of commerce. Fla. Stat. Ann § 501 202(2).

269. Plaintiffs Allen and Rodriguez and the members of the Florida Class are consumers as defined by Fla. Stat. § 501.203. Hyland's homeopathic Products are goods within the meaning of FDUPTA. Defendants are engaged in trade or commerce within the meaning of FDUPTA.

270. Fla. Stat. § 501.204(1) declares unlawful "[u]nfair methods of competition, unconscionable acts or practices, and unfair and deceptive acts or practices in the conduct of any trade or commerce."

271. Fla. Stat. § 501.204(2) states that "due consideration and great weight shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to [section] 5(a)(1) of the Federal Trade Commission Act."

272. Federal decisions provide that "a deceptive practice is one that is likely to mislead consumers." *Jovine v. Abbott Labs., Inc.,* 2011 U.S. Dist. LEXIS 39702, 2011 WL 1376029 (S.D. Fla. Apr. 12, 2011) (quoting *Davis v. Powertel,* 776 So.2d 971, 974 (Fla. Dist. Ct. App. 2000)). The Fourth District Court of Florida has held that an unfair practice is one that "offends established public policy and one that is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers." *Yachting Promotions, Inc. v. Broward Yachts, Inc.,* 792 So.2d 600, 664 (Fla. 4th DCA 2001).

273. Defendants' unfair and deceptive practices are likely to mislead, and have misled, Plaintiffs Allen and Rodriguez and Florida Class who purchased them.

274. Further, Defendants have violated the FDUPTA by engaging in the unfair and deceptive practices as described herein which offend public policies and are immoral, unethical, unscrupulous and substantially injurious to consumers.

275. Plaintiffs Allen and Rodriguez and the Florida Class have been aggrieved by Defendants' unfair and deceptive practices in that they paid for the Products.

276. The damages suffered by Plaintiffs Allen and Rodriguez and the Florida Class were directly and proximately caused by the deceptive, misleading and unfair

practices of the Defendants, as more fully described above.

277. Pursuant to Fla. Stat. § 501.211(1), Plaintiffs Allen and Rodriguez and the Florida Class seek a declaratory judgment and the court order enjoining the above-described wrongful acts and practices of Defendants and for restitution and disgorgement.

278. Additionally, pursuant to Fla. Stat. §§ 501.211(2) and 501.2105, Plaintiffs Allen and Rodriguez and the Florida Class make claims for damages, attorneys' fees and costs.

NINTH CAUSE OF ACTION

VIOLATION OF GEORGIA UNIFORM DECEPTIVE TRADE PRACTICE ACT,

Ga. Code Ann. §§ 10-1-370, *et seq.*

(On Behalf of Plaintiff Xenos and the Georgia Class, as Against All Defendants)

279. Plaintiff Xenos repeats, re-alleges and incorporates by reference each and every allegation contained above as if fully set forth herein.

280. This cause of action is brought pursuant to Georgia Uniform Deceptive Trade Practice Act, O.C.G.A. §§ 10-1-370 to -375 (the "OCGA"). Plaintiff Xenos and members of the Georgia Class are consumers under the OCGA because they purchased the Products for personal or household use and not for resale. *See* OCGA section 10-1-372(b).

281. Defendants violated and continue to violate the OCGA by engaging in the following deceptive trade practices proscribed by section 10-1-372, in transactions with Plaintiff and the Georgia Class which were intended to result in, and did result in, the sale of the Products:

> Represent[ing] that the goods . . . have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have … ***

> Represent[ing] that [the] goods . . . are of a particular standard, quality, or grade . . . , if they are of another; ***
>
> Advertis[ing] goods . . . with intent not to sell them as advertised. ***
>
> Engag[ing] in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

282. Defendants' violated the OCGA, in the course of their business, by representing through their advertisements about the Products that the Products were as advertised, when Defendants knew or should have known, that the representations and advertisements were false, potentially misleading, or potentially confusing, in violation of the OCGA; or any other conduct by Defendants that is likely to create confusion or misunderstanding about the Products.

283. Plaintiff Xenos and members of the Georgia Class, having joint or common interests, were "person[s] likely to be damaged" from Defendants' deceptive trade practices (OCGA 10-1-371(5), -373(a)) because their monetary losses from purchasing the Products flows from actually false, potentially misleading, or potentially confusing misrepresentations.

284. Plaintiff Xenos and other members of the Georgia Class reasonably relied upon the Defendants' deceptive or potentially confusing trade practices as to the quality and attributes of their Products because Defendants manufacture the Products and are the persons most knowledgeable about the Products' qualities in comparison to the Products' advertising; because Defendants sell the Products in the OTC aisle of retail stores, directly to consumers, by which it was reasonable for consumers to rely on the Products' package statements; and because Plaintiffs and other Georgia Class members would not have purchased the Products had they known that Defendants' claims about the Products were either false, potentially confusing or potentially misleading.

285. Defendants' advertising regarding the Products was standard and uniform in that all packages of the Products bear the same representations and alleged misrepresentations.

286. Defendants' deceptive business practices regarding the Products is ongoing, and constitutes a continuing course of conduct in violation of the OCGA because Defendants are still representing that the Products have characteristics, uses, benefits, and abilities that are false, misleading, or confusing, despite Plaintiff's previous notice to Defendants (*see* Ex. 6 attached hereto). *See also Village Auto Ins. Co. v. Rush*, 286 Ga. App. 688 (2007) (classwide treatment appropriate for OCGA claims).

287. Pursuant to OCGA § 10-1-373(a), Plaintiff Xenos and the Georgia Class seek an order of this Court enjoining Defendants from continuing to engage in deceptive business practices with respect to Calms Forte, Teething Tablets, Migraine Headache Relief, ClearAc, Poison Ivy/Oak, and Leg Cramps. Plaintiff Xenos and the Georgia Class also request costs under OCGA 10-1-373(b), and attorney's fees pursuant to OCGA 10-1-373(b), in the court's discretion, if an offer of proof of knowledge of deception is made as to Defendants at trial.

PRAYER FOR RELIEF

Wherefore, Plaintiffs, on behalf of themselves, all others similarly situated and the general public, pray for judgment against all Defendants as to each and every cause of action, including:

A. An order declaring this action to be a proper Class Action and requiring Defendants to bear the costs of Class notice;

B. An order awarding Plaintiffs and the proposed Class members damages in the amount to be determined at trial;

C. An order awarding declaratory and injunctive relief as permitted by law or equity, including enjoining Defendants from continuing the unlawful practices as set forth herein;

D. An order awarding restitution of the purchase price of the Products to Plaintiffs and the proposed Class members; and restitutionary disgorgement of any profits Defendants may have gained from Plaintiffs and the Class, including interest or earnings on the Plaintiffs' and the Class' money that Defendants wrongfully obtained.

E. An order compelling Defendants to engage in a corrective advertising campaign to inform the public concerning the true nature of their Products;

F. An order awarding attorneys' fees and costs to Plaintiffs;

G. An award of punitive damages;

H. An order providing for all other such equitable relief as may be just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: April 26, 2013

By: Ronald A. Marron
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SKYE RESENDES
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Facsimile: (213) 622-6019
Attorneys for Plaintiffs and the Proposed Class

PROOF OF SERVICE

I, the undersigned, declare:

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 707 Wilshire Boulevard, Suite 4100, Los Angeles, California 90017.

On May 3, 2013, I served the foregoing documents described as follows:

Third Amended Complaint for (1) Violation of the Consumers Legal Remedies Act; (2) Violation of the Unfair Competition Law; (3) Violation of the False Advertising Law; (4) Breach of Implied Warranty of Merchantability; (6) Violation of Magnuson-Moss Act; (7) Violation of Florida Deceptive and Unfair Trade Practices Act; and (8) Violation of Georgia Uniform Deceptive Trade Practice Act

Demand for Jury Trial

on the interested parties in this action by placing true copies thereof enclosed in sealed envelopes addressed as stated on the attached service list, as

__x__ BY MAIL:
I am "readily familiar" with the firm's practice of collection and processing correspondence for mailing. Under that practice, it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid at Los Angeles, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

____ BY FEDERAL EXPRESS OR OVERNIGHT COURIER

____ BY ELECTRONIC MAIL:
I served by electronic mail at the email address(es) below:

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on May 3, 2013, at Los Angeles, California.

Patty Davis
(Type or Print Name)

Patty Davis
(Signature)

SERVICE LIST

LAW OFFICES OF RONALD A. MARRON, APLC
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Attorneys for Defendants

Third Amended Complaint
Allen, et al. v. Hyland's, Inc., et al.
12-cv-1150-DMG-MAN
TABLE OF EXHIBITS

EXHIBIT NUMBER	EXHIBIT DESCRIPTION	PAGE NUMBER
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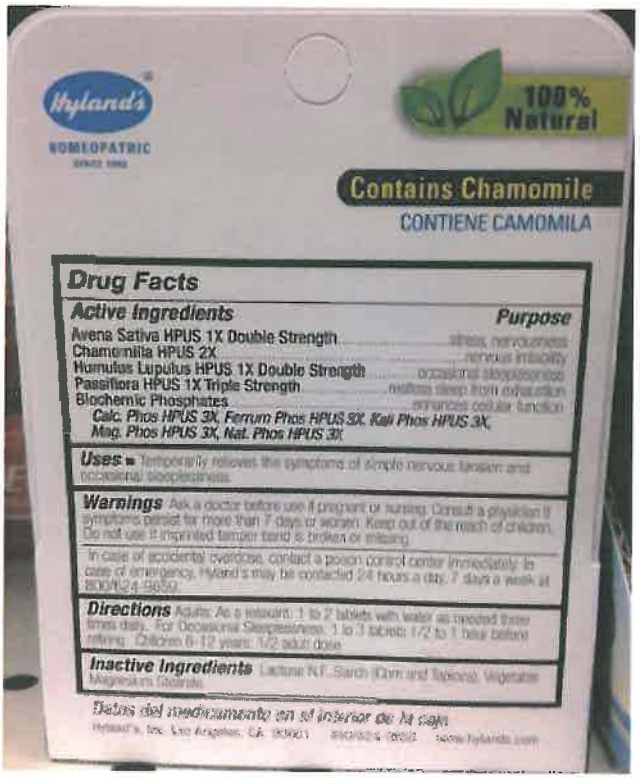
EXHIBIT 1

Third Amended Complaint

Allen, et al. v. Hyland's, Inc., et al.
Case No.: 12-cv-1150-DMG (MAN)

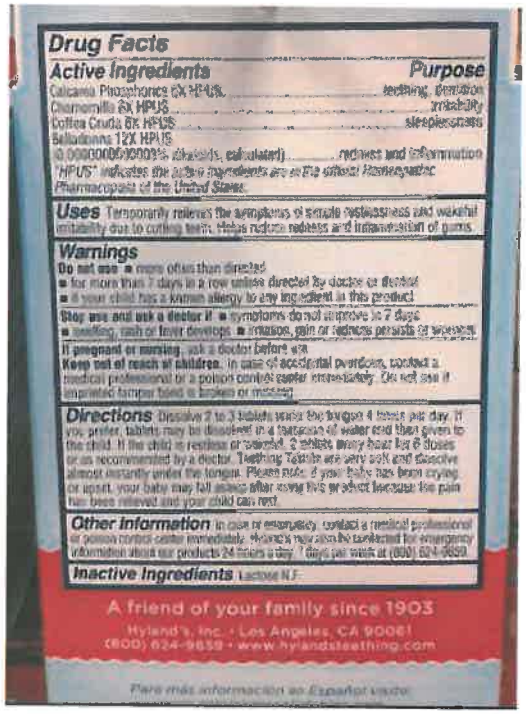
Calms Forté

Hyland's
HOMEOPATHIC
100% Natural
Non-Habit Forming
NO GENERA HÁBITO
CALMS FORTÉ
SLEEP AID
MEDICAMENTO PARA EL SUEÑO
50 Tablets TABLETAS
MADE IN USA
Relieves stress to help you sleep
ALIVIA EL ESTRÉS PARA AYUDAR A CONCILIAR EL SUEÑO
Gentle on the body
SUAVE PARA EL CUERPO
Wake up rested & refreshed!
¡DESPIÉRTESE RENOVADO!

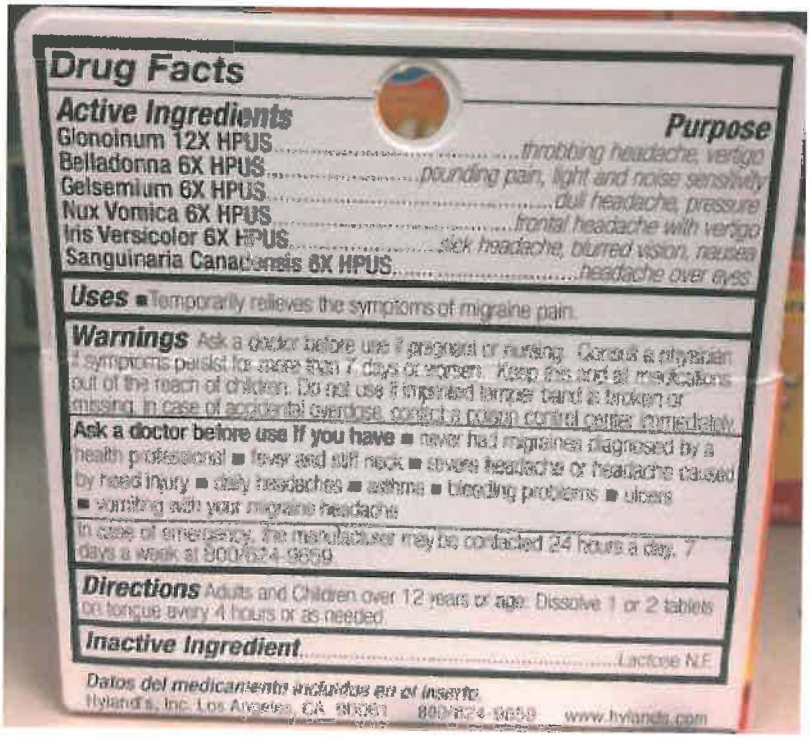

Hyland's
HOMEOPATHIC
100% Natural
Contains Chamomile
CONTIENE CAMOMILA
Drug Facts
Active Ingredients
Purpose
Avena Sativa HPUS 1X Double Strength
Chamomilla HPUS 2X
Humulus Lupulus HPUS 1X Double Strength
Passiflora HPUS 1X Triple Strength
Biochemic Phosphates
Calc. Phos HPUS 3X, Ferrum Phos HPUS 3X, Kali Phos HPUS 3X, Mag. Phos HPUS 3X, Nat. Phos HPUS 3X
Uses
Warnings
Directions
Inactive Ingredients

Hyland's
HOMEOPATHIC
100% Natural
CALMS FORTÉ
SLEEP AID
MEDICAMENTO PARA EL SUEÑO
Relieves stress to help you sleep
ALIVIA EL ESTRÉS PARA AYUDAR A CONCILIAR EL SUEÑO
Gentle on the body
SUAVE PARA EL CUERPO
Wake up rested & refreshed!
¡DESPIÉRTESE RENOVADO!
100 Tablets TABLETAS MADE IN USA

Teething Tablets



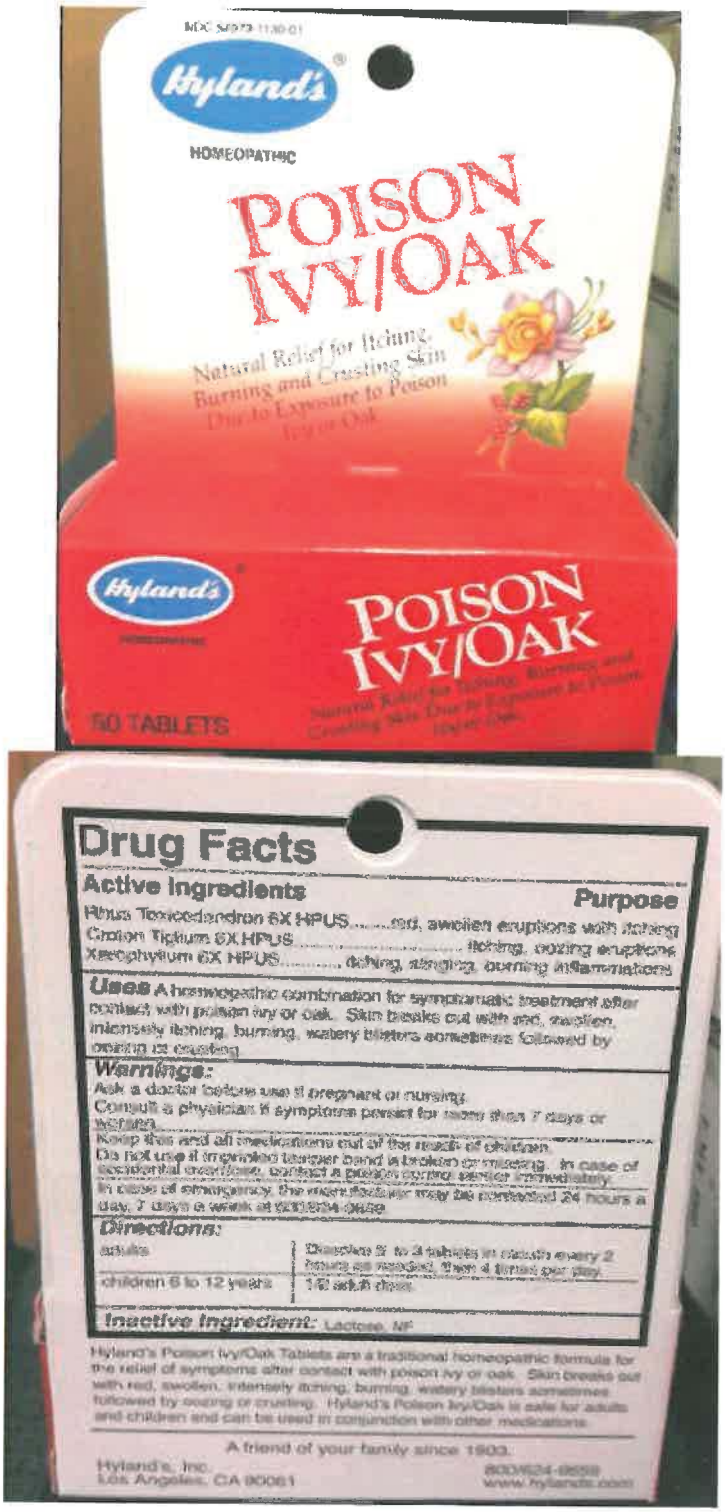
Migrane Headache Relief



ClearAc

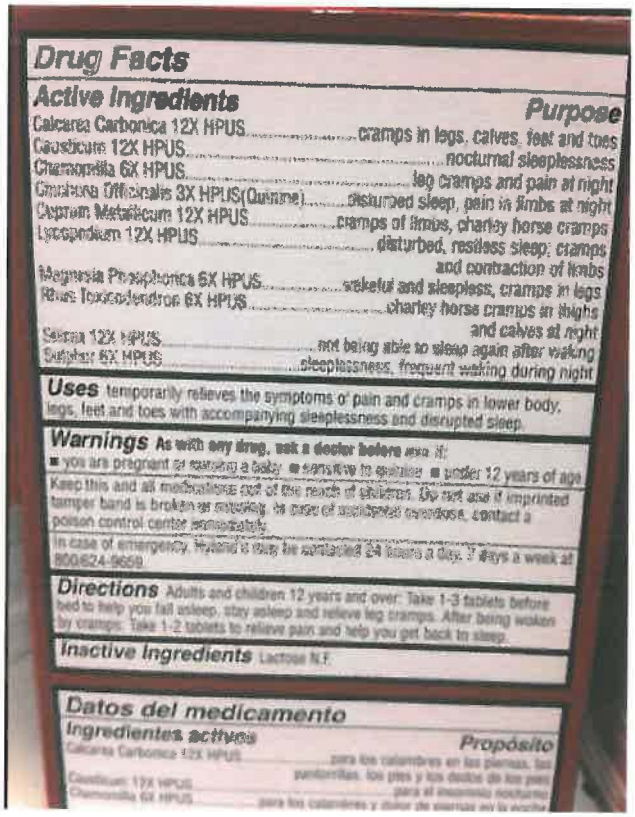
Hyland's
HOMEOPATHIC
NO MESSY MAKEUP OR HARSH CHEMICALS
All natural ClearAc™ helps clear up
acne, pimples, and acne blemishes.
50 TABLETS
ClearAc
Hyland's 100% natural ClearAc acne tablets
Drug Facts
Active Ingredients
Purpose
Echinacea Ang. 6X HPUS
recurring outbreaks, swollen eruptions
Berberis Vulg. 6X HPUS
small pustules, eczematous inflammation
Sulphur Iod. 12X HPUS
unhealthy skin, eruptions with itching
Hepar Sulph. 6X HPUS
acne eruptions that tend to form pustules
Uses helps clear up acne, pimples and acne blemishes.
Warnings:
Ask a doctor before use if
pregnant or nursing a baby
under 3 years of age
If symptoms persist for more than two days or worsen, contact a licensed health care professional.
Keep this and all medications out of the reach of children.
Do not use if imprinted tamper band is broken or missing. In case of accidental overdose, contact a poison control center immediately.
In case of emergency, the manufacturer may be contacted 24 hours a day, 7 days a week at 800/624-9659.
Directions Adults: Dissolve 2 - 3 tablets on tongue every 4 hours or as needed.
Inactive Ingredient: Lactose NF
The homeopathic medicines in ClearAc™ Tablets are indicated for the management and symptomatic relief of symptoms of pimples, blackheads and blemishes associated with common acne (acne vulgaris). ClearAc™ Tablets provide a 100% natural approach to treating this often-embarrassing condition. Like all homeopathic products, ClearAc™ Tablets have no known contraindications or side effects. Use in conjunction with a high quality skin cleanser, such as 100% Natural Hyland's ClearAc™ Cleanser.
A friend of your family since 1903.
Hyland's, Inc.
Los Angeles, CA 90031
800/624-9659
www.hylandls.com

Poison Ivy/Oak Tablets

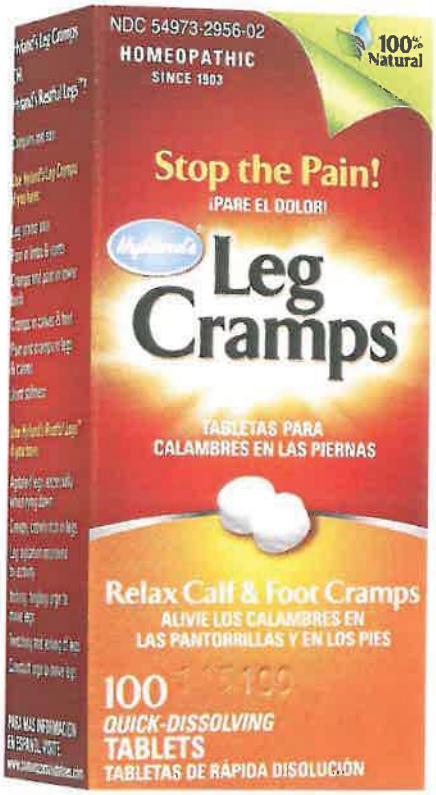


Colic Tablets

Leg Cramps PM with Quinine



Leg Cramps



Drug Facts

Active Ingredients — **Purpose**

Cinchona Off. 3X HPUS (Quinine) ..... pains in limbs & joints
Aconitum Nap. 6X HPUS ..... pains in joints, legs
Gnaphalium Poly. 3X HPUS ..... cramps in calves & feet
Ledum Pal. 6X HPUS ... pain and cramps in legs
Magnesia Phos. 6X HPUS ..... cramps in calves
Rhus Tox. 6X HPUS ... sciatica, pain and stiffness
Viscum Alb. 3X HPUS ... pains in joints, sciatica

Uses Temporarily relieves the symptoms of cramps and pains in lower back and legs.

Warnings **As with any drug, ask a doctor before use if:** ■ you are pregnant or nursing a baby ■ sensitive to quinine ■ under 12 years of age.

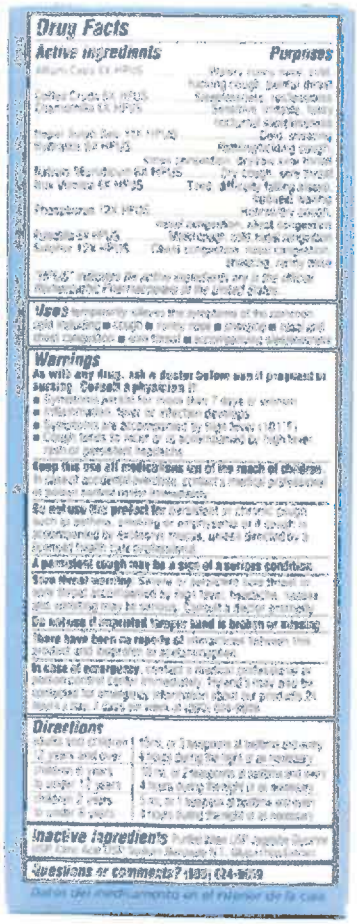
Keep this and all medications out of the reach of children. Do not use if imprinted tamper band is broken or missing. In case of accidental overdose, contact a poison control center immediately. If symptoms persist for more than 7 days or worsen, discontinue use and seek the advice of a licensed healthcare professional.

In case of emergency, Hyland's may be contacted 24 hours a day, 7 days a week at 800/624-9659.

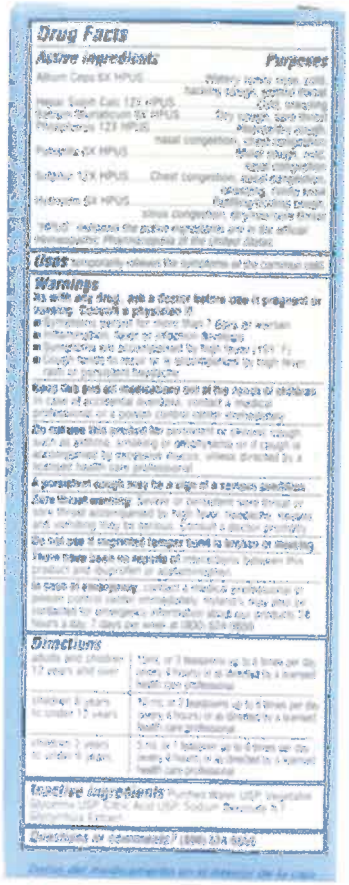
Directions Adults and children ages 12 and over: Dissolve 2-3 tablets under tongue every 4 hours or as needed.

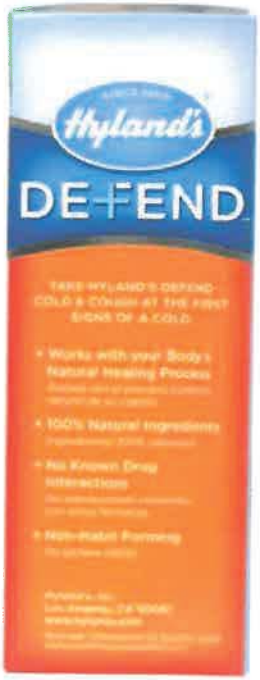
Inactive Ingredients Lactose N.F.

Defend Cold & Cough Night



Defend Cold & Cough





Hyland's Cough

Seasonal Allergy Relief

Drug Facts

Active Ingredients	Purpose
Allium Cepa 6X HPUS	hay fever, watery eyes
Natrum Muriaticum 6X HPUS	sneezing, itchy eyes
Histaminum Hydrochloricum 12X HPUS	sinus pain
Luffa Operculata 12X HPUS	sinus pain, headache
Galphimia Glauca 12X HPUS	sneezing, runny nose
Nux Vomica 6X HPUS	itchy nose & throat

Uses ■ temporarily relieves the symptoms of hay fever or other upper respiratory allergies from mold, animal dander, pollen, ragweed, and grasses

Warnings As with any drug, ask a doctor before use if pregnant or nursing. Consult a physician if symptoms persist for more than 7 days or worsen. Keep out of the reach of children. Do not use if imprinted tamper band is broken or missing. In case of accidental overdose, contact a poison control center immediately. In case of emergency, Hyland's may be contacted 24 hours a day, 7 days a week at 800/624-9659

Directions Adults and children over 12: Dissolve 1 to 2 tablets under the tongue every 4 hours or as needed

Inactive Ingredients Lactose NF

Los datos del medicamento en español se encuentran en el interior de la caja.

Hyland's, Inc. Los Angeles, CA 90061 800/624-9659 www.hylands.com

100% NATURAL
Stop the Pain!
¡PARE EL DOLOR!
Hyland's
Leg Cramps
with Quinine
50 QUICK-DISSOLVING TABLETS
TABLETAS DE RÁPIDA DISOLUCIÓN
TABLETAS CON QUININA
PARA CALAMBRES EN LAS PIERNAS
100% NATURAL
HOMEOPATHIC SINCE 1903
Stop the Pain!
¡PARE EL DOLOR!
Relax Calf and Foot Cramps
ALIVIE LOS CALAMBRES EN LAS PANTIORRILLAS Y EN LOS PIES
Hyland's
Leg Cramps
with Quinine
NDC 54973-2956-01
HOMEOPATHIC
SINCE 1903
50 QUICK-DISSOLVING TABLETS
TABLETAS DE RÁPIDA DISOLUCIÓN
TABLETAS CON QUININA
PARA CALAMBRES EN LAS PIERNAS

Hyland's Leg Cramps
OR
Hyland's Restful Legs™?
Compare and see:
Use Hyland's Legs Cramps if you have:
Leg cramp pain
Pain in limbs & joints
Cramps and pain in lower back, sciatica
Cramps in calves & feet
Pain and cramps in legs & calves
Joint stiffness
Use Hyland's Restful Legs™ if you have:
Agitated legs, especially when lying down
Creepy, crawly itch in legs
Leg agitation improved by activity
Jerking, tingling urge to move legs
Twitching and jerking of legs
Constant urge to move legs
PARA MÁS INFORMACIÓN EN ESPAÑOL, VISITE:
NDC 54973-2956-02
HOMEOPATHIC
SINCE 1903
100% NATURAL
Stop the Pain!
¡PARE EL DOLOR!
Hyland's
Leg Cramps
with Quinine
TABLETAS CON QUININA PARA CALAMBRES EN LAS PIERNAS
Relax Calf & Foot Cramps
ALIVIE LOS CALAMBRES EN LAS PANTORRILLAS Y EN LOS PIES
100
QUICK-DISSOLVING
TABLETS
TABLETAS DE RÁPIDA DISOLUCIÓN

EXHIBIT 1 PAGE 15

Drug Facts

Active Ingredients	Purpose
Cinchona Off. 3X HPUS	pains in limbs & joints
Aconitum Nap. 6X HPUS	pains in joints, legs
Gnaphalium Poly. 3X HPUS	cramps in calves & feet
Ledum Pal. 6X HPUS	pain and cramps in legs
Magnesia Phos. 6X HPUS	cramps in calves
Rhus Tox. 6X HPUS	pain and stiffness
Viscum Alb. 3X HPUS	pains in joints

Uses Temporarily relieves the symptoms of cramps and pains in lower back and legs.

Warnings **As with any drug, ask a doctor before use if:** ■ you are pregnant or nursing a baby ■ sensitive to quinine ■ under 12 years of age.

Keep this and all medications out of the reach of children. Do not use if imprinted tamper band is broken or missing. In case of accidental overdose, contact a poison control center immediately. If symptoms persist for more than 7 days or worsen, discontinue use and seek the advice of a licensed healthcare professional.

In case of emergency, Hyland's may be contacted 24 hours a day, 7 days a week at 800/624-9659.

Directions Adults and children ages 12 and over: Dissolve 2-3 tablets under tongue every 4 hours or as needed.

Inactive Ingredients Lactose N.F.

DATOS DEL MEDICAMENTO EN ESPAÑOL EN EL INTERIOR DE LA CAJA

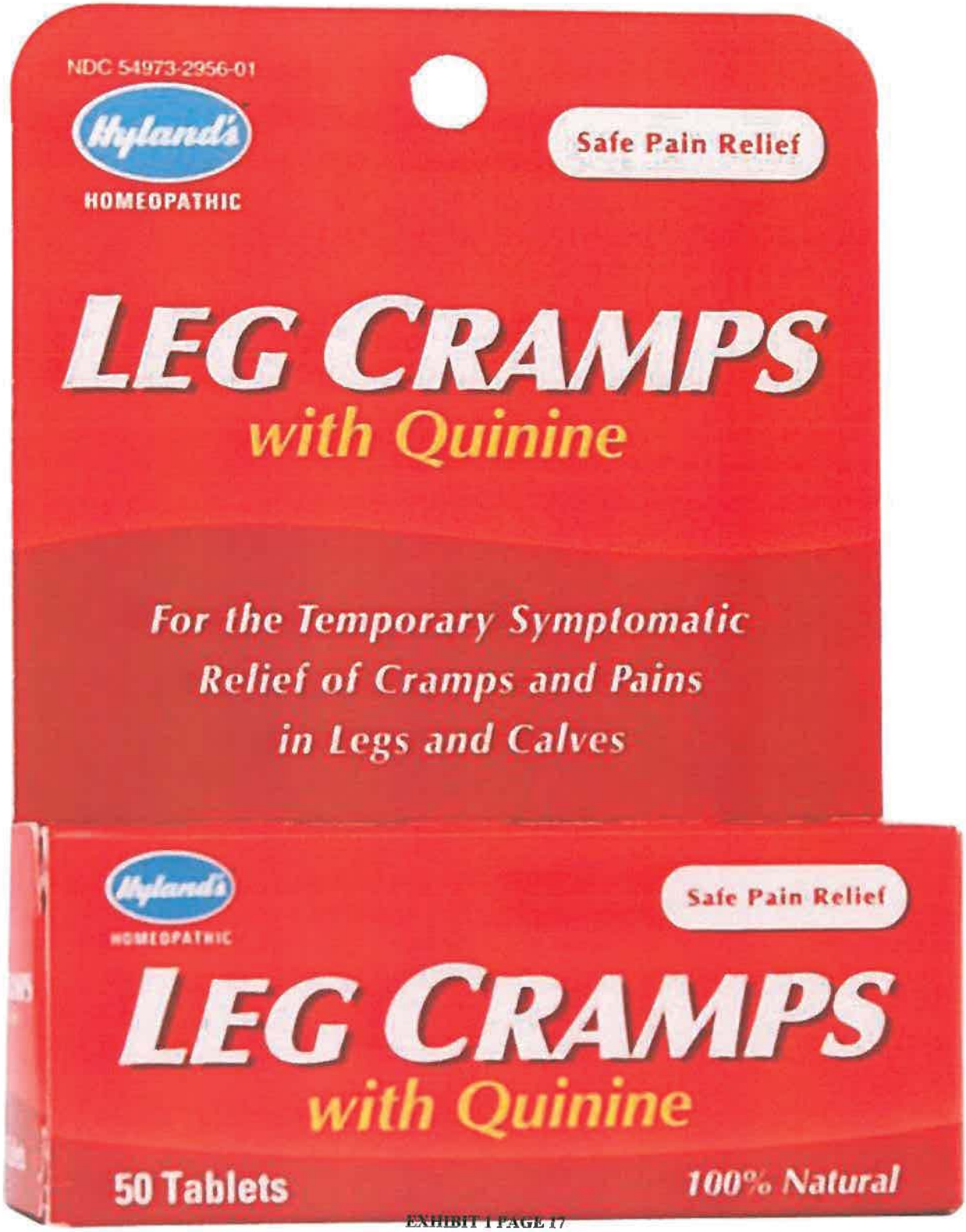

NDC 54973-2956-01
Hyland's
HOMEOPATHIC
Safe Pain Relief
LEG CRAMPS
with Quinine
For the Temporary Symptomatic Relief of Cramps and Pains in Legs and Calves
Hyland's
HOMEOPATHIC
Safe Pain Relief
LEG CRAMPS
with Quinine
50 Tablets
100% Natural

EXHIBIT 2

Third Amended Complaint

Allen, et al. v. Hyland's, Inc., et al.
Case No.: 12-cv-1150-DMG (MAN)

January 04, 2013

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Shoppers Try Natural, Unproven Cold Remedies, Sometimes Without Realizing It

Sentiment:
Slightly Negative
News Source:
The Associated Press State & Local Wire
News Date:
March 4, 2005
Author First Name:
Carla K.
Author Last Name:
Johnson

CHICAGO

Stuffy noses and sore throats are driving many cold sufferers to herbal and homeopathic remedies - sometimes without them even realizing it. Check out the local drugstore and chances are popular alternative products such as Zicam and Airborne are shelved alongside more traditional medicines.

Shopper Beth McClanahan noticed the trend in a downtown Chicago chain drugstore while eyeing packages of Zicam. "I wouldn't have known it was homeopathic," she said looking at the bright orange label. "The name Zicam sounds very scientific."

For drugstore operators, it makes sense to place the remedies where consumers can find them quickly. For the manufacturers, marketing to a wider audience means more sales. But for some experts, the trend is cause for concern.

"I think it's quite confusing for consumers to try to sort out which things have some data showing they actually work," said Dr. Ronald B. Turner, a cold virus expert at the University of Virginia School of Medicine in Charlottesville.

The makers of Zicam and Airborne have paid for their own clinical studies to test their products. But the products have not been reviewed for safety and effectiveness by the Food and Drug Administration, unlike prescription and new over-the-counter drugs. The law allows their sale unless the FDA proves them harmful.

Last month, the Institute of Medicine, citing the popularity of dietary supplements, called for tougher rules to make sure they're safe and effective.

Zicam and other homeopathic products do say on their packaging that they are homeopathic. Zicam, which contains a small amount of zinc, is the nation's third leading nasal spray. Airborne - plugged on Oprah Winfrey's show last fall - is an effervescent tablet containing Chinese herbs, vitamins and echinacea. Its label notes that the FDA has not reviewed its language saying it should be taken at the first sign of cold symptoms.

For cold sufferers, the distinction between what's conventional and what's alternative may not be as important as what they believe works.

"There's a reason for the success of these products. Consumers want them and they're effective," said Rider McDowell, co-founder of the company that created Airborne, an herbal supplement that's a best seller at stores like Walgreens, Osco and CVS Pharmacy.

Steven Dentali of the American Herbal Products Association says his group wants new safety requirements such as mandatory reporting of adverse side effects.

"We think our safety record's going to look pretty good," he said, especially compared to a few prescription drugs.

Herbal products and homeopathic remedies are regulated separately, and the law lays out only a few quality controls and labeling rules.

Homeopathy is based on the idea that tiny amounts of certain natural substances stimulate the body's healing response. Some studies seem to suggest that homeopathic remedies work, but many mainstream doctors consider them quackery.

The trend of integrating "natural" remedies with mainstream drugs on store shelves started in the

What is Homeopathy?

Homeopathy is a system of medicine that is based on the Law of Similars.
Read More »

Attention Parents!

Learn how to treat your child's earaches, fever and flu safely, with homeopathy.

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- Loss of hearing in the Aged
- how to use materia medica database
- Hering's Law or Rule??? There is a difference.
- How Often To Dose and What Potency To Use... Reflections on the subject by E.B. Nash M.D.

more

early 1990s. A homeopathic brand called Hyland's, previously only sold in natural food stores, gets credit.

It started by accident, said Hyland's CEO J.P. Bomeman. A drugstore chain shelved Hyland's remedy for babies' teething pain with the rest of its teething products. The product was selling well.

"We began to get the suspicion that a few products could hop the fence," Bomeman said.

"By 2000, we had a half-dozen products solidly in that class. Then Cold-Eeze and Zicam came on the market and suddenly homeopathy was ubiquitous."

The blurring of lines extends to the product formulas, too.

Cold-Eeze is not as highly diluted as some homeopathic products. A key principle of traditional homeopathy holds that the more diluted a remedy is, the better it works. While Zicam contains one part per 100 of zinc, a Cold-Eeze lozenge contains 13.3 mg of zinc.

"It's not like it's microscopic by any means," said Albert Piechotta, director of marketing and communications for Quigley Corp., maker of Cold-Eeze.

After homeopathic products led the way, the herbal supplement Airborne became the most recent cold remedy crossover success.

"We went out to the mainstream consumer - the working people, the people who really can't afford to be sick," McDowell said. He gives word of mouth credit for Airborne's buzz. But Oprah Winfrey's plug didn't hurt. Winfrey featured McDowell's wife, Victoria Knight-McDowell, on her show last September in a segment on everyday women who created million-dollar products. Knight-McDowell told the story of how she was a teacher tired of catching colds in the classroom, so she created her own product.

In 2004, Airborne - "created by a school teacher" - sold more than $16 million at drugstores, according to Information Resources Inc., a company that tracks retail sales. That was a 200 percent increase over the previous year. Airborne is now considered a "destination product," said Walgreens spokeswoman Tiffani Bruce. "Consumers come to the store and they're sick and they want to find it. So we merchandise it where they're most likely to go first, the cold and flu section."

Back in the Chicago drugstore, McClanahan wasn't ruling out Zicam after learning it was a homeopathic product. "I would try it," she said. But not on this day. She reached for Sudafed. "I need something to clear my head."

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Knowing the consumer is crucial.

NEW YORK -- Customers looking for homeopathic remedies in chain drug stores tend to be much different than the people who rely on natural food stores for these products, those in the industry note.

"Consequently," points out Hyland's Inc. president Dale Nepsa, "there's a vast difference between the way homeopathy is merchandised."

In the natural food store, he notes, shoppers tend to be better educated and have a rudimentary knowledge of homeopathy. In addition, the store personnel are often college educated and more attentive to customers' needs.

"In a chain drug store," Nepsa says, "you don't have the same type of shopper or the same personnel. It's more of a self-service environment."

And that, suppliers who cater to drug stores say, is why the proper merchandising strategy is critical for a retailer to get the most from homeopathic remedies.

"In the mass market arena an all-encompassing homeopathic category is not going to be a destination for consumers," notes Heel USA Inc. retail sales and marketing manager Gibson Archer. "They will go to the category where the products addressing their condition are located."

That approach, suppliers say, ties in with the way drug store consumers shop and has helped homeopathic products gain a greater market share by offering them as just another option for a certain condition rather than so-called weird science.

Ensuring that they have at least one homeopathic or natural alternative to the traditional over-the-counter medications in those categories is becoming more critical for retailers, suppliers point out.

A growing desire by consumers to incorporate more natural products into their health care regimen and the realization that many O-T-Cs can have adverse side effects if used in conjunction with some prescription drugs are making homeopathic remedies more attractive for many people, they note.

And, as the number of categories with homeopathic options grows, most expect homeopathic products to become a

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more important and more prolific part of chain drug store mix.

"One of the biggest hurdles homeopathy has faced is gaining widespread acceptance," A. Nelson & Co. senior brand manager Curt Finckler says. "As more companies move into the mass market that hurdle is getting easier to clear."

---- INDEX REFERENCES ---

NEWS SUBJECT: (Health & Family (1HE30); Nutrition (1NU67); Alternative Healthcare & Wellness (1AL29))

INDUSTRY: (Food & Beverage Production (1FO79); Healthcare Services (1HE13); Pharmacy (1PH23); Healthcare (1HE06); Drugstores (1DR73); Nutraceuticals & Health Foods (1NU55))

Language: EN

OTHER INDEXING: (HYLAND; NELSON CO) (Curt Finckler; Dale Nepsa; Gibson Archer; Nepsa)

KEYWORDS: (Business); (Pharmaceuticals and cosmetics industries); (Retail industry); (Services information); (Services); (Educational aspects); (Pharmaceutical industry); (Pharmaceutical industry - Services); (Pharmaceutical industry - Educational aspects)

COMPANY TERMS: HYLANDS INC

PRODUCT: Pharmaceuticals

SIC: 2834

Word Count: 452
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Volume 29; Issue 17

'Very much a growth category'.

Monks, Richard

[ILLUSTRATION OMITTED]

NEW YORK -- Factors as diverse as growing environmental awareness and a health care system that is failing many Americans are helping spur growth in the sales of homeopathic and natural products.

"It's been an uphill struggle for some time," says Heel USA Inc. retail sales and marketing manager Gibson Archer. "The number of uninsured Americans and the trend toward natural and organic products have led to increased interest in homeopathic products in a variety of categories."

Sales of homeopathic products through the natural food channel and the mass market are approaching $800 million a year, those in the industry claim, and no channel is growing faster than drug stores.

"This is very much a growth category," points out Curt Finckler, senior brand manager for the United States wing of British homeopathic supplier A. Nelson & Co., whose Rescue Remedy and Rescue Sleep formulas have done well since being added to the mix at Walgreen Co. earlier this year. "Consumers are becoming more aware of homeopathy and are seeking these products out."

As a result more players are entering the market.

For example, Heel, which has been in business since the 1930s, made its initial foray into the mass market with its Traumeel, a topical formula used to treat injuries ranging from sprains and contusions to inflammatory conditions.

Despite more players encroaching on their territory, suppliers that have been in the mass market for years say they welcome the addition of these new suppliers.

"When we were the only voice in the mass market it was difficult to get our message across," states Dale Nepsa, president of Hylands Inc., which has been marketing homeopathic products to chain drug stores, supermarkets and discounters since 1992. "As more people become involved, it is becoming much easier."

Hylands offers one of the most extensive lineups with some stores carrying as many as two dozen of its items across a wide variety of product areas.

Nepsa points out that in some Rite Aid Corp. stores with GNC nutrition centers in them, Hylands is represented in-line in as many as a dozen product areas, and another 18 products are merchandised in the GNC area.

Rite Aid's homeopathic mix is indicative of the direction homeopathy is headed in chain drug stores across the country.

When homeopathy is incorporated into the mix, suppliers of these products say, they not only sell well but help bring more consumers into stores because they provide a wider range of treatment options in the various categories where they are merchandised.

"A lot of retailers are seeing that this is a necessary part of their mix," Nelson's Finckler says. "Mass marketers and drug stores see the opportunity and recognize that consumers are looking for these complementary therapies."

Still, those in the industry note, not all consumers know what they are buying when they purchase a homeopathic item. In most cases, they say, shoppers are attracted to an item's all-natural qualities before they are drawn to its homeopathic heritage. In many cases homeopathy is not even a factor in their decision to buy a product.

"A lot of people who are buying homeopathy in food, drug and mass don't know the products are homeopathic," Hylands' Nepsa says. "They just know the products work for them and are safe to use with other drugs."

---- INDEX REFERENCES ---

COMPANY: RITE AID CORP; GNC CORP; WALGREEN CO

NEWS SUBJECT: (Health & Family (1HE30); Sales & Marketing (1MA51); Alternative Healthcare & Wellness (1AL29); Business Management (1BU42); Sales (1SA20))

INDUSTRY: (Healthcare Services (1HE13); Pharmacy (1PH23); Healthcare (1HE06); Drugstores (1DR73))

REGION: (North America (1NO39); Americas (1AM92); USA (1US73))

Language: EN

OTHER INDEXING: (GNC; HEEL; HEEL USA INC; HYLANDS; HYLANDS INC; ILLUSTRATION; NELSON; NELSON CO; RITE AID; RITE AID CORP; WALGREEN CO) (Curt Finckler; Dale Nepsa; Finckler; Gibson Archer; Nepsa)

KEYWORDS: (Business); (Pharmaceuticals and cosmetics industries); (Retail industry); (Market information - general); (Forecasts, trends, outlooks); (Homeopathy); (Homeopathy - Supply and demand); (Homeopathy - Forecasts and trends); (Homeopathy - Materia medica and therapeutics)

Word Count: 665
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June 21, 2004

Volume 26; Issue 11

Hyland's offers 'natural remedies that work'.

LOS ANGELES -- With consumers becoming increasingly accepting of homeopathic remedies, Hyland's Inc. has established itself as the brand most often found in chain drug stores across North America.

"Consumers have created the demand for natural, safe, effective medicines, and retailers have listened and are now offering the products that their customers want to see," comments chairman and chief executive officer Jay Borneman.

Over the years, he says, Hyland's has reinforced its position in chain drug stores by increasing the number of SKUs it offers the trade class and by growing its market share in the channel. In fact, the company has a long heritage of doing business with drug chains.

"Hyland's Teething Tablets have been merchandised in chain drug stores since World War II," he notes. "We have aggressively marketed our products in chain drug stores for the past 12 years, and that experience, combined with the brand loyalty from crossover consumers from the natural food class of trade, gives us an advantage with consumers."

In the time its products have been on drug store shelves the supplier has been able to maintain a strong position in a handful of categories. Its Hyland's Leg Cramps with Quinine and Hyland's Teething Tablets rank at or near the top of their respective categories.

The company's line of approximately 200 medicines is tailored specifically for drug store customers, says Borneman. Hyland's corporate parent, Standard Homeopathic Co., manufactures more than 2,500 homeopathic medicines, but not all of them are applicable to mass market outlets.

"We limit the Hyland's products sold in chain drug, traditional food and discounters to the top 10 to 15 SKUs," he remarks. ' 'We focus on consumers' need for natural medicines that work, and strive to place them in the correct over-the-counter section within the store so that shoppers can find them."

To help customers become more accepting of its offerings, Hyland's has developed what Borneman calls "accessible, consumer-friendly" packaging.

"You don't need to know anything technical about homeopathy to use Hyland's products," he says, "and yet you receive the same benefit as someone who is very knowledgeable."

Besides helping consumers overcome a wide range of illnesses, Hyland's aids retailers through a variety of merchandising, marketing and cooperative advertising programs designed to help them get the maximum turns and the best return on investment possible.

"If Hyland's products are merchandised in the right section--i.e., not in vitamins and herbal but in analgesics, baby care and other O-T-C categories --we can achieve excellent synergies for the retailer," Borneman says.

In recent years the supplier has made a concerted effort to expand its offerings, adding two or three new items to its line annually. Among its highest-profile launches recently have been Hyland's Seasonal Allergy Tablets, Hyland's Migraine Headache Relief Tablets and Hyland's Leg Cramps Ointment.

Earlier this year two new items--Hyland's Earache Drops (a companion product to the company's Hyland's Earache Tablets) and Hyland's Complete Flu C are--were introduced.

"The most obvious reason a retailer should carry our products," Borneman notes, "is that we provide effective, high-quality natural remedies that work without side effects and are affordable to the consumer. Hyland's consistently delivers the lowest cost per dose in its category."

Also, he says, users of the company's products tend to be very brand-loyal and will seek out stores that carry its line.

But, Borneman stresses, perhaps the best reason for a retailer to include the Hyland's lineup in its health care mix is that homeopathic remedies and alternative medicine are rapidly becoming part of a growing number of consumers' health care regimens.

"As consumers look for more natural medicines they are sending a clear message that there is a better answer to health care than acetaminophen disguised as a cold, flu, leg cramp, arthritis, headache, sinus and cough medicine," he says.

Hyland's Inc.

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Fax: (310) 516-8579

Primary business:

HEALTH CARE

Homeopathic remedies

ALLEN000637

Marketplace booth #1532

---- INDEX REFERENCES ---

COMPANY: STANDARD HOMEOPATHIC CO

NEWS SUBJECT: (Health & Family (1HE30); Alternative Healthcare & Wellness (1AL29))

INDUSTRY: (Healthcare Services (1HE13); Pharmacy (1PH23); Healthcare (1HE06); Drugstores (1DR73))

REGION: (California (1CA98); North America (1NO39); Americas (1AM92); USA (1US73))

Language: EN

OTHER INDEXING: (LEG CRAMPS OINTMENT; LOS ANGELES CALIF; STANDARD HOMEOPATHIC CO) (Borneman; Complete Flu; Consumers; Dale Nepsa; Hyland; Jay Borneman; Marketplace; P.O. Box; Primary; Web) (United States)

KEYWORDS: (Business); (Pharmaceuticals and cosmetics industries); (Retail industry); (Marketing procedures); (Product introduction); (New Products/Services); (Product introduction); (Marketing); (Homeopathy); (Homeopathy - Marketing); (Pharmaceutical industry); (Pharmaceutical industry - Product introduction); (Pharmaceutical industry - Marketing); (Homeopathy - Materia medica and therapeutics)

COMPANY TERMS: HYLANDS INC

PRODUCT: Pharmaceuticals

SIC: 2834

Word Count: 852
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2 of 100 DOCUMENTS

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Chain Drug Review

March 4, 2002

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ACC-NO: 83521131

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HEADLINE: Key to driving sales: Location, location, location.;
Homeopathy;
homeopathic remedies need to be displayed with other products in drug stores, not in separate section;
Brief Article

BODY:

NEW YORK -- Location is the key to the successful merchandising ofhomeopathic remedies in chain drug stores, according to the leading suppliers in the category.

"The more savvy retailers slot **homeopathic** items next to their regular allopathic products in the sets and soon discover that they are garnering incremental sales," comments Jay Borneman, president of Hyland's Inc.

Homeopathic medications are reasonable alternatives to their allopathic counterparts, he asserts, and need to be considered on the basis of the condition they treat.

"For example, the main competition for our Hyland's teething tablets are other teething preparations -- not other **homeopathic** preparations," says Borneman.

Executives at other leading suppliers in the category, including Boericke & Tafel Inc.'s (**B&T's**) director of marketing, Susan Backer, concur.

"It is wrong to make homeopathy a separate section, because that is not the way people shop," she notes. If they have a cold or flu, they will visit the cough/cold section."

Retail pharmacies that lump **homeopathic** products in a "natural" section are missing out on substantial profits, according to Backer.

To counter that, buyers must not look at the **homeopathic** consumer as monolithic, Borneman says. "What we need to be talking to buyers about is which products can be integrated into specific O-T-C sectionsto boost the chances of their customers finding a truly useful product," he remarks.

A number of Hyland's products are among the leaders in their respective product segments. For example, Hyland's teething tablets is theNo. 2 brand in unit sales, while Hyland's Leg Cramps with Quinine, aproduct that has proven effective in alleviating leg pain, tops the category with a 70% market share.

Another popular **homeopathic** product in drug stores is **B&T's** Arniflora amica gel, a natural botanical remedy widely used to relieve pain, muscle ache and stiffness, bruising and swelling.

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In addition, the company recently launched Allergiemittel AllerAide, a natural **homeopathic** remedy for allergy relief.

The cough/cold/allergy category is a natural for **homeopathic** medications. One product designed to give fast multi-symptom relief for the common cold and influenza is BioRight International Inc.'s Arizona Sun natural cold medicine.

Parents are particularly interested in finding remedies to treat their children's ailments without creating other problems, and **homeopathic** remedies often provide a welcome answer, according to suppliers.

For example, Hyland's earache tablets have been clinically shown to reduce earache symptoms in the first 48 hours of each episode, and they work without side effects. In addition, each package contains a reference booklet written by a physician and a pharmacist.

Young mothers and other consumers in chain drug outlets are different than shoppers in natural food stores, notes Dale Nepsa, Hyland's vice president.

"The chain drug channel is basically a self-service environment," he observes, "and consumers are generally not as conversant in the category. What they seek is a product that will truly help their or their child's affliction, one that's not invasive and won't contraindicate with other medications."

Backer agrees. "We find the most effective way to reach people is not by getting into the cumbersome ins and outs of how homeopathy functions, but by conveying the message that it truly works -- that theyare getting effective medications backed by science."

Suppliers in the category agree that chain drug stores have a built-in advantage in the homeopathy business because of the trade class'reputation as a health care provider as well as the presence and availability of knowledgable pharmacists.

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Hyland's takes natural approach to health care.

LOS ANGELES -- Hyland's Inc., the nation's oldest manufacturer of homeopathic medicine, has seen tremendous growth in recent years, as more consumers look to natural medicines for a convenient, safe and affordable alternative to costly prescription drugs.

According to a study released in 2004 by the National Center for Complementary and Alternative Medicine and the National Center for Health Statistics, 36% of adults in the United States are using some form of complementary and alternative medicine. This, combined with a growing interest in the natural products marketplace, has drawn many consumers to the Hyland's brand.

J.P. Borneman, Hyland's chairman and chief executive officer, says the company's success is grounded in providing consumers with unprecedented over-the-counter access to the natural alternatives they are seeking.

"Hyland's provides consumers with convenient and reliable health care solutions by making natural medicines available in mainstream retailers nationwide," says Borneman. "Our ever growing selection of gentle and effective medicines relieve pain and help families feel better.

"And as more consumers better understand how homeopathy works, the demand for Hyland's products continues to increase and distribution becomes even more widespread."

Hyland's carefully formulated medicines have been developed to address adult health needs and the needs of their children, with options for infants as well as children and adults of all ages.

Homeopathy, in the form of Hyland's Earache Drops and Tablets, can be a wonderful ally for parents who want to adhere to the 48-hour wait-and-see period (WASP) recommended by the American Academy of Pediatrics. These medicines target earache pain, are safe for both children and adults, and provide options for those concerned about building up unnecessary resistance to antibiotics.

It is no secret that Americans continue to be plagued by sleep issues. In the wake of highly publicized side effects often caused by expensive prescription sleep aids, a growing number of families are turning to Hyland's Calms Forte, which promises 100%-natural relief of nervous tension and insomnia without side effects or the danger of addiction.

Hyland's president Dale Nepsa notes that in recent years Calms Fort8 has become one of the fastest-growing items in

drugs stores, showing that the medicine is providing consumers with a much-needed, effective natural sleep aid option.

Hyland's is also addressing the needs of the millions who suffer from agitated legs, an alarmingly common condition that affects up to 45 million Americans. According to the company, the recent introduction of Hyland's Restful Legs offers consumers the first and only all-natural O-T-C medication that provides relief from leg jerks, twitches, crawling, itching, tingling leg sensations and the constant urge to move the legs.

Recognizing the tremendous growth of the Hispanic population in the U. S.--now the nation's largest ethnic minority group--and the ongoing interest in all-natural medicines among the Hispanic community, Hyland's is on the leading edge of helping chain drug stores address the cultural and educational needs around the effectiveness of natural medicines.

Just this year the company repackaged its popular Teething Tablets and Colic Tablets to include specific Spanish-language drug information to meet the needs of this growing demographic looking to drug stores for products that are similar to the ones they are used to seeing in their native countries.

In an effort to increase awareness and familiarity among children and parents, Hyland's recently partnered with Universal Studios Consumer Products Group to become the first homeopathic company to license a character in its labeling with the introduction of new Curious George packaging on popular Sniffles 'n Sneezes 4 Kids and Calms Forte 4 Kids. Again, consumers are reacting very positively to a recognizable character that conveys feelings of comfort and familiarity--emotions that make it less stressful when young children are feeling under the weather.

Providing mainstream access to effective medicines that are affordable has been the key to helping consumers find relief for their various health issues. As demand for natural products continues to grow, Hyland's products can now be found nationwide in traditional grocery stores, convenience stores and major pharmacies in addition to natural food outlets across the country.

This increased availability ensures that consumers everywhere can find a natural, safe and affordable solution for their health and wellness needs, according to the company.

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Primary business: HEALTH CARE Homeopathic products

Marketplace booth #1238

---- INDEX REFERENCES ---

COMPANY: HISPANIC AND ASIAN MARKETING COMMUNICATION RESEARCH INC; STANDARD HOMEOPATHIC CO; HISPANIC

NEWS SUBJECT: (Social Issues (1SO05); Alternative Healthcare & Wellness (1AL29); Minority & Ethnic Groups

(1MI43); Health & Family (1HE30))

INDUSTRY: (Healthcare Practice Specialties (1HE49); Internal Medicine (1IN54); Sleep & Sleep Disorders (1SL50); Neurology (1NE95); Healthcare (1HE06))

REGION: (North America (1NO39); USA (1US73); Americas (1AM92); California (1CA98))

Language: EN

OTHER INDEXING: (AMERICAN ACADEMY; COLIC TABLETS; EARACHE DROPS AND TABLETS; HISPANIC; HOMEOPATHIC; HYLAND; NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE; NATIONAL CENTER FOR HEALTH STATISTICS; RESTFUL LEGS; STANDARD HOMEOPATHIC CO; TEETHING TABLETS; UNIVERSAL STUDIOS CONSUMER PRODUCTS GROUP) (Borneman; Dale Nepsa; J.P. Borneman; Primary; Sniffles; Web)

KEYWORDS: (Business); (Pharmaceuticals and cosmetics industries); (Retail industry); (Marketing procedures); (Growth); (Marketing); (Health care industry); (Health care industry - Growth); (Health care industry - Marketing)

COMPANY TERMS: HYLANDS INC

PRODUCT: HEALTH SERVICES

SIC: 8000

Word Count: 983
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END OF DOCUMENT

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EXHIBIT 3

Third Amended Complaint

Allen, et al. v. Hyland's, Inc., et al.
Case No.: 12-cv-1150-DMG (MAN)

Hyland's, Inc. Product	"Active" Ingredient	Dilution	Purpose
Calms Forté	Avena Sativa	1X Double Strength	Stress, nervousness
	Chamomilla	2X (= 1/100 dilution)	Nervous irritability
	Humulus Lupulus	1X Double Strength	Occasional sleeplessness
	Passiflora	1X Triple Strength	Restless sleep from exhaustion
	Biochemic Phosphates		Enhances cellular function
	Calc. Phos	3X (= 1/1,000 dilution)	
	Ferrum Phos	3X (= 1/1,000 dilution)	
	Kali Phos	3X (= 1/1,000 dilution)	
	Mag. Phos	3X (= 1/1,000 dilution)	
	Nat. Phos	3X (= 1/1,000 dilution)	
Teething Tablets	Calcarea Phosphorica	6X (= 1/1,000,000 dilution)	Teething, dentition
	Chamomilla	6X (= 1/1,000,000 dilution)	Irritability
	Coffea Cruda	6X (= 1/1,000,000 dilution)	Sleeplessness
	Belladonna	12X (0.0000000000003% alkaloids, calculated)	Redness and inflammation
Migraine Headache Relief	Glonoinum	12X (= 1/1,000,000,000,000 dilution)	Throbbing headache, vertigo
	Belladonna	6X (= 1/1,000,000 dilution)	Pounding pain, light and noise sensitivity
	Gelsemium	6X (= 1/1,000,000 dilution)	Dull headache, pressure
	Nux Vomica	6X (= 1/1,000,000 dilution)	Frontal headache with vertigo
	Iris Versicolor	6X (= 1/1,000,000 dilution)	Sick headache, blurred vision, nausea
	Sanguinaria Candensis	6X (= 1/1,000,000 dilution)	Headache over eyes

ClearAc	Echinacea Ang.	6X (= 1/1,000,000 dilution)	Recurring outbreaks, boil-like and swollen eruptions
	Berberis Vulg.	6X (= 1/1,000,000 dilution)	Small pustules, eczematous inflammation
	Sulphur Iod	6X (= 1/1,000,000 dilution)	Unhealthy skin, pimply eruptions with itching
	Hepar Sulph	6X (= 1/1,000,000 dilution)	Acne eruptions that tend to head up an form pustules
Poison Ivy/Oak Tablets	Rhus Toxicdendron	6X (= 1/1,000,000 dilution)	Red, swollen eruptions with itching
	Croton Tiglium	6X (= 1/1,000,000 dilution)	Itching, oozing eruptions
	Xerophylium	6X (= 1/1,000,000 dilution)	Itching, stringing, burning inflammations
Colic Tablets	Dioscorea	3X (= 1/1,000 dilution)	Colic pains better from motion
	Chamomilla	3X (= 1/1,000 dilution)	Restlessness & irritability
	Colocynthis	3X (= 1/1,000 dilution)	Abdominal pain caused by gas
Leg Cramps with Quinine	Aconitum Nap.	6X (= 1/1,000,000 dilution)	Pains in limbs & joints
	Gnaphalium Poly.	3X (= 1/1,000 dilution)	Cramps in calves & feet
	Ledum Pal.	6X (= 1/1,000,000 dilution)	Pain and cramps in legs
	Cinchona Officinalis	3X (Quinine) (= 1/1,000 dilution)	Pains in limbs & joints
	Viscum Alb.	3X (= 1/1,000 dilution)	Pains in joints

	Magnesia Phosphorica	6X (= 1/1,000,000 dilution)	Cramps in calves
	Rhus Toxicodendron	6X (= 1/1,000,000 dilution)	Pain and stiffness
Leg Cramps	Cinchona Off.	3X (Quinine) (= 1/1,000 dilution)	Pains in limbs & joints
	Aconitum Nap.	6X (= 1/1,000,000 dilution)	Pains in joints, legs
	Gnaphalium Poly.	3X (= 1/1,000 dilution)	Cramps in calves & feet
	Ledum Pal.	6X (= 1/1,000,000 dilution)	Pain and cramps in legs
	Magnesia Phos.	6X (= 1/1,000,000 dilution)	Cramps in calves
	Rhus Tox	6X (= 1/1,000,000 dilution)	Sciatica, pain and stiffness
	Viscum Alb.	3X (= 1/1,000 dilution)	Pains in joints, sciatica
Defend Cold & Cough Night	Allium Cepa	6X (= 1/1,000,000 dilution)	Watery runny nose, cold, hacking cough, painful throat
	Coffea Cruda	6X (= 1/1,000,000 dilution)	Relieves sleeplessness, restlessness
	Chamomilla	6X (= 1/1,000,000 dilution)	Relieves sensitive, irritable, fussy, nocturnal sleeplessness
	Hepar Sulph Calc	12X (= 1/1,000,000,000,000 dilution)	Relieves cold, sneezing
	Hydrastis	6X (= 1/1,000,000 dilution)	Relieves rattling or tickling cough, sinus congestion, dry/raw/sore throat
	Natrum Muriaticum	6X (= 1/1,000,000 dilution)	Relieves dry cough, sore throat

	Nux Vomica	6X (= 1/1,000,000 dilution)	Relieves tired, difficulty falling asleep, frequent waking
	Phosphorous	12X (= 1/1,000,000,000,000 dilution)	Relieves hoarse/dry cough, nasal congestion, chest congestion
	Pulsatilla	6X (= 1/1,000,000 dilution)	Relieves moist cough, cold, nasal congestion
	Sulphur	12X (= 1/1,000,000,000,000 dilution)	Relieves chest congestion, nasal congestion, sneezing, runny nose
Defend Cold & Cough	Allium Cepa	6X (= 1/1,000,000 dilution)	Watery runny nose, cold, hacking cough, painful throat
	Hepar Sulph Calc	12X (= 1/1,000,000,000,000 dilution)	Cold, Sneezing
	Natrum Muriaticum	6X (= 1/1,000,000 dilution)	Dry Cough, Sore Throat
	Phosphorus	12X (= 1/1,000,000,000,000 dilution)	Hoarse/dry cough, nasal congestion, chest congestion
	Pulsatilla	6X (= 1/1,000,000 dilution)	Moist cough, cold, nasal congestion
	Sulphur	12X (= 1/1,000,000,000,000 dilution)	Chest congestion, nasal congestion, sneezing, runny nose
	Hydrastis	6X (= 1/1,000,000 dilution)	Rattling/tickling cough, sinus congestion, dry/raw/sore throat

Hyland's Cough	Bryonia	3X (= 1/1,000 dilution)	Dry, hacking cough from irritation in upper trachea
	Causticum	3X (= 1/1,000 dilution)	Cough with raw soreness of chest and sensation of mucous under sternum
	Hepar Sulph	3X (= 1/1,000 dilution)	Choking cough with rattling and croaking; feeling of splinter in throat
	Antimonium Tartaricum	6X (= 1/1,000,000 dilution)	Helps in raising mucous and moist coughs
Seasonal Allergy Relief	Allium Cepa	6X (= 1/1,000,000 dilution)	Hay fever, watery eyes
	Natrum Muriaticum	6X (= 1/1,000,000 dilution)	Sneezing, itchy eyes
	Histaminum Hydrochloricum	12X (= 1/1,000,000,000,000 dilution)	Sinus pain
	Luffa Operculata	12X (= 1/1,000,000,000,000 dilution)	Sinus pain, headache
	Galphimia Glauca	12X (= 1/1,000,000,000,000 dilution)	Sneezing, runny nose
	Nux Vomica	6X (= 1/1,000,000 dilution)	Itchy nose & throat

Products	Challenged Statements
Calms Forté	"100% Natural," "Sleep Aid," "For Restless or Wakeful Sleep from Exhaustion," "For Stress, Nervousness or Nervous Headache," "For Drowsiness with Incomplete Sleep," "For Nervous Irritability," "Biochemic Phosphates for Enhancing Cellular Function," "Wake up Rested & Refreshed," "Relieves Stress to Help you Sleep," "HPUS" and "Homeopathic"
Teething Tablets	"Teething Tablets," "Relieve Pain and Irritability from Teething," "Soft Tablets Dissolve Instantly," "100% Natural," "Temporarily Relieves the Symptoms of Simple Restlessness and Wakeful Irritability Due to Cutting Teeth," "No Artificial Flavors, Dyes or Parabens," "Helps Reduce Redness and Inflammation of Gums," "HPUS," "HPUS indicates the active ingredients are in the official Homeopathic Pharmacopeia of the United States" and "Homeopathic"
Migraine Headache Relief	"100% Natural," "Migraine Headache Relief," "Quick Dissolving Tablets," "Aspirin Free," "Relieves Pressure, Throbbing, Light + Noise Sensitivity," "Temporarily Relieves the Symptoms of Migraine Pain," "HPUS," "Homeopathic"
ClearAc	"Acne Tablets," "Gentle on Skin No Harsh Chemicals," "100% Natural," "A 100% Natural Approach," "All Natural ClearAc Helps Clear up Acne, Pimples and Acne Blemishes," "Medicated skin cleanser," "high quality skin cleanser" "Indicated for the management and symptomatic relief of symptoms of pimples, blackheads and blemishes associated with common acne (acne vulgaris)," "Homeopathic," "HPUS" and "The homeopathic medicines in ClearAc Tablets . . ."
Poison Ivy/Oak Tablets	"Poison Ivy/Oak Tablets," "Natural Relief for Itching, Burning and Crusting Skin Due to Exposure to Poison Ivy or Oak," "Relief of symptoms after contact with poison ivy or oak," "Safe for adults and children," "A homeopathic combination for Symptomatic Treatment after Contact with Poison Ivy or Oak,"

Products	Challenged Statements
	"Homeopathic," "HPUS"
Colic Tablets	"Colic Tablets," "Symptomatic Relief for Colic in Children," "No Side Effects," "100% Natural," "Relieves Colic Gas Pain and Irritability," "Homeopathic," "HPUS"
Leg Cramps with Quinine	"100% Natural," "Leg Cramps with Quinine" (same in Spanish), "Stop the Pain!" (same in Spanish), "Natural Relief for Cramps and Pains in Lower Back and Legs" (same in Spanish), "Safe Pain Relief," "Temporarily Relieves the Symptoms of Cramps and Pains in Lower Back and Legs," "Relax Calf & Foot Cramps," "For the Temporary Symptomatic Relief of Cramps and Pains in Legs and Calves," "Sciatica," "Leg Cramp Pain," "Joint Stiffness," "Cramps and Pain in Lower Back," "Homeopathic," "Use Hyland's Leg Cramps if you have: leg cramp pain, pain in limbs & joints, cramps and pain in lower back, sciatica, cramps in calves & feet, pain and cramps in legs & calves, joint stiffness," "Hyland's Leg Cramps is a traditional homeopathic formula for the relief of symptoms of cramps and pains in lower back and legs often made worse by damp weather," "Working without contraindications or side effects," "Hyland's Leg Cramps is safe for adults and can be used in conjunction with other medications," "Hyland's Leg Cramps stimulates your body's natural healing response to relieve symptoms," "HPUS"
Leg Cramps	"Leg Cramps," "Stop the Pain!" (same in Spanish), "Relax Calf & Foot Cramps" (same in Spanish), "100% Natural", "Quinine," "Temporarily relieves the symptoms of cramps and pains in lower back and legs," "Homeopathic"
Defend Cold & Cough Night	"Defend Cold & Cough Night," "100% Natural," "100% Natural Ingredients" (same in Spanish), "Safe and Effective Relief of: Sleeplessness, Congestion, Cough, Sore Throat, Sneezing" (same in Spanish), "Temporarily relieves the symptoms of the

Products	Challenged Statements
	common cold," "Dye Free, Alcohol Free, Sugar Free" (same in Spanish), "No known drug interactions" (same in Spanish), "Homeopathic," "HPUS indicates the active ingredients are in the official Homeopathic Pharmacopeia of the United States"
Defend Cold & Cough	"Defend Cold & Cough," "Safe and Effective Relief of Nasal Congestion, Cough, Sore Throat, Sneezing" (same in Spanish), "Dye Free, Alcohol Free, Sugar Free" (same in Spanish), "100% Natural" (same in Spanish), "100% Natural Ingredients," "No Known Drug Interactions" (same in Spanish), "Homeopathic," "HPUS indicates the active ingredients are in the official Homeopathic Pharmacopeia of the United States"
Hyland's Cough	"Natural Relief for Coughs Due to Colds" (same in Spanish), "100% Natural" (same in Spanish), "Relief of symptoms of cough due to common cold, especially coughs where assistance is raising mucous is necessary" (same in Spanish), "A traditional homeopathic formula for the relief of symptoms of cough due to colds," "Working without contraindications or side effects," "Safe for adults and children," "Homeopathic," "HPUS," "HPUS indicates the active ingredients are in the official Homeopathic Pharmacopeia of the United States"
Seasonal Allergy Relief	"Seasonal Allergy Relief," "100% Natural," "For Indoor & Outdoor Allergies" (same in Spanish), "Temporarily relieves the symptoms of hay fever or other upper respiratory allergies from mold, animal dander, pollen, ragweed, and grassed," "Homeopathic," "HPUS"

EXHIBIT 4

Third Amended Complaint

Allen, et al. v. Hyland's, Inc., et al.
Case No.: 12-cv-1150-DMG (MAN)

U.S. Food and Drug Administration
Protecting and Promoting Your Health

Inspections, Compliance, Enforcement, and Criminal Investigations

Standard Homeopathic Company, Inc. 4/29/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 38-11

April 29, 2011

Mark S. Phillips, President
Standard Homeopathic Company
210 W 131st St
Los Angeles, CA 90061-1618

Dear Dr. Phillips:

During our September 8, 2010 to October 28, 2010 inspection of your pharmaceutical manufacturing facility Standard Homeopathic Company, located at 210 W 131st Street, Los Angeles, California, investigators from the Food and Drug Administration (FDA or Agency) identified significant violations of Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations (C.F.R.), Parts 210 and 211. These violations cause your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 351(a)(2)(B)) in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP.

In addition, FDA reviewed your firm's labeling submitted to the export certificate program for homeopathic drug products and labeling and marketing information found on your website at the internet address http://www.hylands.com[1]. This review revealed that your firm is marketing drugs that are misbranded in violation of sections 502 and 503 of the Act (21 U.S.C. §§ 352 and 353).

We have reviewed your firm's response of November 10, 2010, and note that it lacks sufficient corrective actions.

CGMP Deviations

Specific violations observed during the inspection include, but are not limited, to the following:

1. Your firm does not have adequate written procedures for production and process controls designed to assure that the drug products you manufacture have the identity, strength, quality, and/or purity they purport or are represented to possess [21 C.F.R. § 211.100(a)].

For example, your firm's mixing times in the approved records for Belladonna, Chamomilla, Calcarea Phos., and Coffea Cruda 1X dilutions, and the approved record for Hyland's Teething Tablets, are not supported by adequate process validation.

We acknowledge your action to recall the Hyland's Teething Tablets and your commitment to ensure that a

(b)(4) tablet batch records will accurately reflect the times established in your mixing studies conducted with the 150 gallon **(b)(4)** and the 15 gallon **(b)(4)** mixers. However, we cannot consider your response adequate until you scientifically justify the use of surrogates, such as **(b)(4)** , in your validation study instead of the actual ingredients used in your products. There is no assurance that the surrogates have similar mixing characteristics, particle size distribution, or other potentially important characteristics to accurately simulate the **(b)(4)** mixing process.

2. Your firm failed to establish time limits for the completion of each phase of production to assure the quality of the drug product [21 C.F.R. § 211.111].

For example, your firm has failed to establish hold times for the 1X dilutions of Chamomilla and Belladonna. Hyland's Teething Tablets (lot **(b)(4)**) were manufactured on May 26, 2010, using a Chamomilla 1X dilution (lot **(b)(4)**) and a Belladonna 1X dilution (lot **(b)(4)**) that were manufactured on January 27, 2010, and February 18, 2010, respectively. Your firm's hold times of **(b)(4)** for the Belladonna 1X dilution and **(b)(4)** for the Chamomilla 1X dilution are not supported by any scientific evidence showing the lack of blend segregation.

3. Your firm failed to conduct testing on in-process materials for identity, strength, quality, and purity during the production process, at commencement or completion of significant phases, or after storage for long periods [21 C.F.R. § 211.110(c)].

For example, your firm failed to conduct in-process testing to ensure blend uniformity for Belladonna 1X dilution (lots **(b)(4)**). Your firm only conducted an examination for color, odor, and taste.

4. Your firm failed to test each lot of a component with a potential for microbiological contamination that is objectionable in view of its intended use [21 C.F.R. § 211.84(d)(6)].

For example, your firm fails to analyze and test your botanically derived components for the presence of likely objectionable organisms prior to the manufacture of drug products, including those intended for infants and toddlers. Although your firm commits to test components used in the Hyland's Homeopathic Teething Tablets for total plate counts, Escherichia coli, Salmonella species, yeast, mold, and Clostridium botulinum, you have not committed to assess botanically derived components for other possible objectionable organisms such as Bacillus cereus. Furthermore, you response failed to address the other botanical components used to manufacture other marketed products, such as Hyland Colic Tablets, which are also intended for use in infants and toddler populations.

5. Your firm has not thoroughly investigated the failure of a batch or any of its components to meet its specifications whether or not the batch has already been distributed [21 C.F.R. § 211.192].

For example, your firm's Quality Control Unit (QCU) failed to identify the root cause and assess the impact on other related lots when approximately 62 kilograms of Restful Legs Tablets (lot **(b)(4)**) were rejected due to the presence of brown specs on April 8, 2010.

In your response, your firm states that you will train your QCU on Root Cause Analysis and Corrective Action Prevention. However, your response is inadequate because your firm has failed to extend the investigation to other lots and products that may be associated with this failure.

This is a repeat violation from the January 2010 inspection.

Misbranding [§§ 503(b)(4) and 301(a)]

FDA reviewed your labeling submission to the Export Certificate Program dated August 5, 2010 and your website at the internet address http://www.hylands.com[2] in January 2011. FDA reviewed your firm's labeling and website information for homeopathic drug products, including but not limited to: "Leg Cramps with Quinine Tablets," "Nighttime Cold 'n Cough 4 Kids," and "Bedwetting Tablets."

Your product labeling and website document the intended uses of your products including, but not limited t the following:

Leg Cramps with Quinine Tablets: "Viscum Album 3X HPUS – for symptoms of . . . sciatica" "Rhus Toxicodendron 6X HPUS – for . . . Sciatica with pains in tendons and ligaments."

Nighttime Cold 'n Cough 4 Kids: "Pulsatilla 6X HPUS - spasmodic cough . . . " "Sulphur 12X HPUS . . . burning runny nose"

Bedwetting Tablets: "Rhus Aromatica 3X HPUS - for incontinence with constant dribbling in children." "Belladonna 3X HPUS (0.0003% Alkaloids) – for frequent and profuse urination with sensation of motion in bladder. For incontinence and continuous dropping."

Based on the above labeling and claims, these products are drugs under section 201(g)(1)(B) of the Act (2 U.S.C. § 321(g)(1)(B)), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, and under section 201(g)(1)(C) of the Act (21 U.S.C. § 321(g)(1)(C)), because they are intended to affect the structure or function of the body.

Section 503(b)(1) of the Act (21 U.S.C. 353(b)(1)) identifies criteria for determining the prescription status of a product. The products listed above are prescription drugs within the meaning of Section 503(b)(1) of the Act because they are intended to treat diseases that require diagnosis and treatment by a physician or are intended to provide treatment for symptoms usually caused by an underlying disease process that requires diagnosis and treatment by a physician. Because they may be dispensed only by prescription of a licensed practitioner, these products are misbranded under Section 503(b)(4) of the Act (21 U.S.C. § 353(b)(4)) in that their labels fail to bear the symbol, "Rx only." [1] Your marketing of these misbranded products violates Section 301(a) of the Act (21 U.S.C. § 331(a)).

We recognize that these products are labeled as homeopathic drugs with active ingredients measured in homeopathic strengths.[2] The definition of "drug" in section 201(g)(1) of the Act (21 U.S.C. § 321(g)(1)) includes articles recognized in the official Homeopathic Pharmacopeia of the United States (HPUS), or any supplement to it. Homeopathic drugs are subject to the same regulatory requirements as other drugs; nothing in the Act exempts homeopathic drugs from any of the requirements related to adulteration, labeling, misbranding, or approval. We acknowledge that many homeopathic drugs are manufactured and distributed without FDA approval under enforcement policies set out in the Agency's Compliance Policy Guide entitled, "Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15)" (the CPG). As its title suggests, the CPG identifies specific conditions under which homeopathic drugs may ordinarily be marketed; thus, in order to fall under the enforcement policies set forth in the CPG, a homeopathic product must meet the conditions set forth in the CPG. One of those conditions is compliance with Section 503(b) of the Act. Under the CPG, only homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed OTC. Homeopathic products offered for conditions not amenable to OTC use must be marketed as prescription products.

Misbranding [§§ 502(a) and 301(a)]

Your firm's products "Leg Cramps with Quinine" and "Leg Cramps PM with Quinine" are misbranded under Section 502(a) of the Act because the labeling is false and misleading. The labeling of "Leg Cramps with Quinine" and "Leg Cramps PM with Quinine" prominently displays the ingredient "Quinine" on the front of the package and in the name of the product. The labeling is false and misleading because it suggests that quinine is the active ingredient when in fact the active ingredient is "Cinchona Officinalis."

Further, the label indentifies this active ingredient as "Cinchona Officinalis 3X HPUS (Quinine)." According to the HPUS, although Cinchona bark contains quinine, it also contains other related alkaloids. Your selective identification of only one of the alkaloids in Cinchona bark is false and misleading because it incorrectly suggests that there is only one alkaloid in Cinchona bark.

Your marketing of these misbranded products violates Section 301(a) of the Act (21 U.S.C. § 331(a)).

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist a your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence and the occurrence of other violations. It is your responsibility to assure compliance with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts. Additionally, FDA may withhold approval of requests for export certificates, or approval of pending drug applications listing your facility, until the above violations are corrected. FDA may re-inspect to verify corrective actions have been completed.Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have

taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations and copies of supporting documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the date by which you will have completed the correction. Additionally, your response should state if you no longer manufacture or distribute any of the products that are the subject of this letter, including Hyland Teething Tablets, and provide the date(s) and reason(s) you ceased production and if or when you plan to resume production.

Your reply should be sent to: Blake Bevill, Compliance Branch Director, U.S. Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612-2445. If you have question a regarding any issue in this letter, please contact Marco Esteves, Compliance Officer at (949) 608-4439.

Sincerely,

/s/

Alonza E. Cruse

District Director

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[1] We note that the Agency's Compliance Policy Guide entitled, "Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15)" (the CPG) states that, in accordance with § 503(b)(1) of the Act, homeopathic drug products offered for conditions that require diagnosis or treatment by a licensed practitioner must bear the prescription legend, "Caution: Federal law prohibits dispensing without prescription." The CPG was issued by the agency in 1988. In 1997, Congress enacted the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105-115); Section 126 of FDAMA amended section 503(b)(4) of the Act to require that the label of a prescription drug product must bear, at a minimum, the symbol "Rx only."

[2] For example, the label for "Bedwetting Tablets" includes the ingredients "Equisetum Heymale 3X HPUS, Rhus Aromatic 3X HPUS, Belladonna 3X HPUS."

Page Last Updated: 05/16/2011
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Links on this page:

1. http://www.hylands.com
2. http://www.hylands.com

EXHIBIT 5

Third Amended Complaint

Allen, et al. v. Hyland's, Inc., et al.
Case No.: 12-cv-1150-DMG (MAN)

HPUS
HOMOEOPATHIC PHARMACOPOEIA of the United States

The Homœopathic Pharmacopœia of the United States

Welcome Ron Marron

Monograph

ALLIUM CEPA **0080** **ALLC**

NAME IN CONTEMPORARY USE: ***Allium cepa* L.**

SYNONYMS:

Latin: *Cepa vulgaris* Renault
English: Onion
Spanish:
French: Oignon
German: Zwiebel
Italian:

BIOLOGICAL CLASSIFICATION: Family Liliaceae (Lily Family)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
A bulbous biennial plant, the bulb being compressed, round or oblong. The scape appears the second year, is 0.9 to 1.2 m high, straight and smooth. The flowers are terminal, umbelliferous and greenish-white. The red variety is used preferably.

RANGE AND HABITAT:
Native of Hungary. Numerous varieties are universally cultivated.

PREPARATION AND CLASSIFICATION:
Tincture of the mature bulb (Class C or Class M).

MEDICATION:
OTC: TINC.
Ext. Use: TINC.
Rx: N/A
HPN: N/A

First approval date: 04/30/2012
Last update date: 06/22/201

HPUS HOMOEOPATHIC PHARMACOPOEIA of the United States

The Homœopathic Pharmacopœia of the United States

Welcome Ron Marron

Monograph

ANTIMONIUM TARTARICUM **0177** **ANTT**

NAME IN CONTEMPORARY USE: **Antimony potassium tartrate**

SYNONYMS:

Latin: Kalii antimoniotartras, Antimonii et Kalii tartras, Tartarus emeticus, Antimonium et kali tartaricum, Tartarus stibiatus, Kalium stibyltartaricum

English: Tartar emetic, Antimony tartrate

Spanish:

French: Antimoniotartrate de potassium, Emétique

German: Brechweinstein, Antimonyl Kaliumtartrat

Italian:

BIOLOGICAL CLASSIFICATION:

CHEMICAL FORMULA AND MOLECULAR WEIGHT:
_____$C_8H_4K_2O_{12}Sb_2 \cdot 3H_2O$ [m.w. 613.81 (anhydrous)]

DESCRIPTION:
Colorless, odorless, transparent crystals, or white powder. The crystals effloresce upon exposure to air and do not readily rehydrate even on exposure to high humidity. Freely soluble in boiling water; soluble in water and in glycerin; insoluble in alcohol. Its solutions are acid to litmus.

RANGE AND HABITAT:

PREPARATION AND CLASSIFICATION:
Solution 1/100 in water (Class B).
Trituration (Class F).

MEDICATION:
OTC: 3X
Ext. Use: N/A
Rx: 1X
HPN: N/A

First approval date: 06/01/2010
Last update date: 08/16/2012

HPUS
HOMOEOPATHIC PHARMACOPOEIA of the United States

The Homœopathic Pharmacopœia of the United States

Welcome Ron Marron

Monograph

AVENA SATIVA **0290** **AVSH**

NAME IN CONTEMPORARY USE: Avena sativa L.

SYNONYMS:

Latin:

English: Oats

Spanish:

French: Avoine

German: Hafer

Italian:

BIOLOGICAL CLASSIFICATION: Family Poaceae (Grass Family)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
An erect, tufted, annual grass, 0.6-1.5 m high, with smooth, glabrous stems. The bi-seriate leaves emerge from hard nodes on the stem and surround the stem with smooth, glabrous leaf sheaths. The ligule at the end of the leaf sheath is approximately ovate, 3 to 5 mm long, and with fine, narrowly triangular, pointed teeth at the upper end. The linear-lanceolate lamina is finely rough on both sides, particularly at the margin, up to 45 cm long, and 10 to 15 mm (sometimes 20 mm) wide. The inflorescence is a loose, terminal panicle 15-30 cm long. The solitary, terminal spikelets are slender-pedicelled and pendulous, with 2 (occasionally 3) flowers. The two glumes that subtend the florets are seven- to eleven-veined. The rachilla is glabrous, but may be hairy below the lowest flower. The sometimes sparsely hairy lemma is 12 to 15 mm long, green, yellowish-white to brown, red or black, pointed at the apex, toothless or with two or more toothlets on the veins towards the tip. The lower part of the lemma is smooth, glossy and awnless, or bears (usually on the lower flowers) a bent, rough, 15 to 40 mm long awn that emerges from the middle of the dorsal side. The usually straight palea is shorter than the lemma and displays a dense row of hairs on each of the two keels. The floret contains two small lodicules, three stamens, and the superior, hairy tricarpellary ovary, which is capped by a short style bearing a feathery bifid stigma.

RANGE AND HABITAT:
A cultigen, apparently derived from Avena fatua L. (Wild Oats). It is cultivated in moist, temperate climates throughout the world for the edible grain, and sometimes occurs as an escape along roadsides and railways.

PREPARATION AND CLASSIFICATION:
Tincture of the aerial parts of the flowering plant (Class C or Class O).

MEDICATION:
OTC: TINC.
Ext. Use: N/A
Rx: N/A
HPN: N/A

First approval date: 11/01/2010
Last update date: 12/15/2010

HPUS HOMOEOPATHIC PHARMACOPOEIA of the United States

The Homœopathic Pharmacopœia of the United States

Welcome Ron Marron

Monograph

BELLADONNA **1033** **BELL**

NAME IN CONTEMPORARY USE: ***Atropa belladonna* L.**

SYNONYMS:

Latin: *Belladonna baccifera* Lam., *Atropa lethalis* Salisb., *Belladonna trichotoma* Scop.

English: Deadly nightshade, Banewort, Death's herb, Dwale, Poison black cherry

Spanish:

French: Belladone

German: Tollkirsche

Italian:

BIOLOGICAL CLASSIFICATION: Family Solanaceae (Nightshade Family)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
A large, bushy, perennial herb, with a thick, fleshy, juicy, branched and spreading root, pale-brown externally, white internally, when fresh. The stems are erect, 0.9 to 1.5 m high, thick, cylindrical, smooth, dividing at first into three, then dichotomous, frequently branching, the youngest shoots pubescent. The leaves are numerous, alternate below, in pairs above, one larger than the other, short stalked, 7.6 to 23 cm long, ovate, entire, dark green in color. The flowers, May to August, are solitary (rarely two or three together), axillary, stalked, drooping, with the pedicel as long as or longer than the calyx, with short, glandular hairs; the calyx is five cleft. The corolla is bell-shaped, about 2.5 cm long, cut into five lobes, dull reddish-purple, tinged with pale green below. The glossy, black berries ripen in September. The whole plant is fetid when bruised, and of a dark purplish color.

RANGE AND HABITAT:
Native of southern and central Europe, Asia Minor, and Algeria, where it is common in ruins and waste places. Cultivated in North America.

PREPARATION AND CLASSIFICATION:
Tincture of the whole plant, when beginning to flower
(Class C or Class M).

MEDICATION:
OTC: 3X
Ext. Use: TINC.
Rx: TINC.
HPN: N/A

First approval date: 10/01/2011
Last update date: 09/18/2012

HPUS HOMOEOPATHIC PHARMACOPOEIA of the United States

The Homœopathic Pharmacopœia of the United States

BRYONIA **1080** **BRYA**

NAME IN CONTEMPORARY USE:
_____***Bryonia alba* L.**
_____***Bryonia cretica* L. subsp. *dioica* (Jacq.) Tutin**

SYNONYMS:

Latin:

English: White bryony, Black-berried bryony

Spanish:

French: Couleuvrée, Bryone

German: Zaunrübe

Italian:

BIOLOGICAL CLASSIFICATION: Family Cucurbitaceae (Gourd Family)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
A perennial, climbing, herbaceous vine, with long, spiral tendrils sprouting from the leaf stalks. The bright green leaves are alternate, rough, cordate, and divided into 5 lobes, with the middle lobe being the longest. The small, greenish-yellow flowers of *B. alba* are monecious, appearing in June and July, in axillary racemes, the male flower being on long peduncles, and the female larger than the male. The flowers of *B. cretica* are dioecious. The male flowers are in loose, stalked cymes, 3 to 8 flowers per cyme, the stamens having one-celled, yellow anthers. The female flowers are generally either sessile or with very short stalks - two to five together. The corollas in each case consist of five petals, cohering only at the base. The outer green calyx is widely bell-shaped. The berries of *B. alba* are globular and black, about 6 mm in diameter, while the *B. cretica* berries are red. The fleshy root of both species is napiform and poorly ramified, 0.6 m long, 5 to 10 cm thick, with numerous transverse striations, yellowish-gray externally, yellowy-white to white internally, with a bitter "rough" taste, and a nauseating odor which disappears on drying. The fresh root exudes a small quantity of latex.

RANGE AND HABITAT:
Middle and south of Europe, in vineyards and woods.

PREPARATION AND CLASSIFICATION:
Tincture of the root (Class C).

MEDICATION:
OTC: 3X
Ext. Use: TINC.
Rx: TINC.
HPN: N/A

First approval date: 08/01/2008
Last update date: 09/24/2012

HPUS
HOMOEOPATHIC PHARMACOPOEIA of the United States

The Homœopathic Pharmacopœia of the United States

Welcome Ron Marron

Monograph

CALCAREA CARBONICA **2030** **CALC**

NAME IN CONTEMPORARY USE: **Calcium carbonate of Hahnemann**

SYNONYMS:

Latin: Calcarea carbonica ostrearum, Calcarea ostreica, Calcarea ostrearum

English: Impure calcium carbonate, Oyster shells

Spanish:

French: Calcaire d'huître

German: Austernschalenkalk

Italian:

BIOLOGICAL CLASSIFICATION:
_____*Crasostrea angulata* Lamk.
_____*Crasostrea gigas* Lamk.
_____*Ostrea edulis* L.
_____(Family Ostreidae)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
The substance used by Hahnemann was a natural carbonate of lime as it exists in the oyster shell. Take well selected, tolerably thick oyster shells, clean and break in a wedgewood or porcelain mortar, select the pure white portions which exist between the exterior and inner surfaces, wash carefully in water, dry over a water bath, and reduce to a fine powder.

RANGE AND HABITAT:

PREPARATION AND CLASSIFICATION:
Trituration (Class F).
Liquid attenuation (Class H): 8X and higher.

MEDICATION: **OTC:** 1X
Ext. Use: N/A
Rx: N/A
HPN: N/A

First approval date: 11/01/2010
Last update date: 08/20/2012

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CALCAREA PHOSPHORICA **2043** **CAPH**

NAME IN CONTEMPORARY USE: Calcium phosphate

SYNONYMS:

Latin: Calcii phosphas, Tricalcii phosphas

English: Precipitated calcium phosphate, Tribasic calcium phosphate

Spanish:

French: Phosphate tricalcique

German: Calciumphosphat

Italian:

BIOLOGICAL CLASSIFICATION:

CHEMICAL FORMULA AND MOLECULAR WEIGHT: $Ca_5(PO_4)_3$ 502.31

DESCRIPTION:
A Tribasic calcium phosphate consists of a variable mixture of calcium phosphates [$Ca_5(OH)(PO_4)_3$ (m.w. 502.31) and $Ca_3(PO_4)_2$ (m.w. 310.20)] having the approximate composition $10CaO{\cdot}3P_2O_5{\cdot}H2O$. A white, amorphous, tasteless, odorless powder; sparingly soluble in water, insoluble in alcohol, soluble in nitric and hydrochloric acids. At a strong red heat, it melts without decomposition, yielding, on cooling, a porcelain-like mass. It is contained in bones (80%), and extracted from them by dissolving in hydrochloric acid and precipitating with ammonium hydroxide.

RANGE AND HABITAT:

PREPARATION AND CLASSIFICATION:
Trituration (Class F).
Liquid attenuation (Class H): 8X and higher.

MEDICATION:

OTC: 1X
Ext. Use: 1X
Rx: N/A
HPN: N/A

First approval date: 11/01/2010
Last update date: 12/15/2010

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CAUSTICUM **2107** **CAUS**

NAME IN CONTEMPORARY USE: **Hahnemann's Causticum**

SYNONYMS:

Latin: Tinctura acris sine kali

English:

Spanish:

French: Causticum, Causticum d'Hahnemann

German: Causticum

Italian:

BIOLOGICAL CLASSIFICATION:

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
Take recently burnt lime and immerse it for one minute in water. Then place it in a well-dried glass mortar. It will give off a considerable amount of heat and vapor before quickly crumbling into a powder. Mix 60 g of this powder with an equal quantity of potassium bisulfate (melted beforehand at red-hot heat, then cooled again) in a porcelain mortar. Add 60 g of boiling water; put this thick mass into a glass distilling apparatus. Distill until the preparation is perfectly dry. The distillation product obtained weighs about 45 g and constitutes the starting material. It is a clear, colorless liquid with a soapy odor and a more or less styptic taste, miscible with water and alcohol.

RANGE AND HABITAT:

PREPARATION AND CLASSIFICATION:
Solution 1/10 in 55% alcohol (Class A).

MEDICATION: **OTC:** 3X
Ext. Use: N/A
Rx: 1X
HPN: N/A

First approval date: 08/01/2012
Last update date: 08/07/2012

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CHAMOMILLA **2127** **CHAM**

NAME IN CONTEMPORARY USE: Matricaria recutita L.

SYNONYMS:

Latin: Anthemis vulgaris L., Chamomilla vulgaris S.F. Gray, Chamomilla officinalis Koch., Chysanthemum chamomilla Bernh., Matricaria suaveolens L., Matricaria chamomilla L.

English: German chamomile, Single chamomile, Bitter chamomile, Wild chamomile

Spanish:

French: Camomille allemande, Matricaire camomille

German: Echte Kamille

Italian:

BIOLOGICAL CLASSIFICATION: Family Asteraceae (Sunflower Family)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
An aromatic, annual glabrous plant, with large, woody, fibrous root. The stem is erect, 0.3-0.6 m high, solid, smooth, shining, strongly striate, with long, slender branches. The leaves are numerous, alternate, sessile, amplexicaul; the upper simple, the others bi- or tri-pinnatifid; the segments strap-shaped, narrow and minutely pointed. The inflorescence is a corymb of terminal capitula which are about 2 cm in diameter, solitary on each ramification. The ligulate marginal flowers are white, with ligules which hang over one side. The flower head is hemispherical, about 6 mm in diameter, composed of a few ray florets and numerous disk florets, carried on a receptacle surrounded by an involucre. The involucre is green, formed of two to three rows of lanceolate, glabrous, and imbricated bracts with blunt apices and scarious whitish edges. Ray florets, which usually have fallen off, have 10 to 20 pistils; corolla is ligulate, white, but darkens at a length of 6 mm and a width of 3 mm, 3-toothed and transversed by four main veins. Disk florets are yellow, perfect, about 2 mm in length; corolla is tubular with five teeth; five stamens are epipetalous and syngenesious. Receptacle is hollow, hemispherical in the young and conical in the older flower head, 3 to 10 mm in width, and lacking paleae. Achene is narrower at the base and obliquely cut off at the base, and has three to five striations on its concave side; on the outer side it is rounded, with no ribs, and occasional glandular dots. The plant has thin, spindle-shaped roots that do not branch much.

RANGE AND HABITAT:
Found in waste or cultivated ground throughout Europe, except the extreme north, extending through northern Asia to the peninsula of India; also in Australia, where it is a troublesome weed.

PREPARATION AND CLASSIFICATION:
Tincture of the whole flowering plant (Class C or Class N).

MEDICATION:
OTC: TINC.
Ext. Use: TINC.
Rx: N/A
HPN: N/A

First approval date: 11/01/2010
Last update date: 12/15/2010

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CROTON TIGLIUM **2245** **CROT**

NAME IN CONTEMPORARY USE: ***Croton tiglium* L.**

SYNONYMS:

Latin: *Croton jamalgota* Buch., *Tiglium officinale* Klotzsch

English: Croton seed, Purging nut

Spanish: Piñones de Maluco

French: Graine de croton

German: Purgierkörner

Italian:

BIOLOGICAL CLASSIFICATION: Family Euphorbiaceae (Spurge Family)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
An evergreen tree, 4.5-6 m high, with a smooth bark and slender branches, having alternate, petiolate leaves, and green, racemose, terminal flowers, appearing from August to September. The*poisonous* seeds are oblong-ovate, blunt at either end, slightly flattened on one side, 10-15 mm long and 6-10 mm wide The outer integument is a dull, reddish-brown, or more yellowish, with irregular blackish speckling, or else completely dark; it peels easily, uncovering a second blackish and horn-like membrane. A slight keel projects out from each side, rendering the seeds somewhat angular in appearance; the transverse section is three- or four-angled with more or less bulging sides. A fine, not always distinct, rib runs lengthwise down the upper third of the blunt-convex dorsal surface of the seed, sometimes accompanied by two lateral ribs. A fine, strand-like raphe, which separates the 2 flatter sides of the ventral surface, runs along the ventral surface to the hilum. A small, light-colored wart-like structure is occasionally visible at the point where these longitudinal lines meet at the upper, often slightly thicker end. Inside the hard brittle black husk is a third thin, smooth, silver-gray membrane that tends to remain attached to the oily, slightly glossy, yellowish, bluntly four-edged kernel. The kernel is odorless, with a mild and oleaginous taste that becomes nauseous and persistently acrid (*Caution*: *poisonous*!). Transverse and longitudinal sections show the embryo within a well developed endosperm, the slightly concave halves of which are held together loosely at the lateral margins.

RANGE AND HABITAT:
East Indies and the Coromandel coast.

PREPARATION AND CLASSIFICATION:
Tincture of the dried seeds (Class C).

MEDICATION:
OTC: 3X
Ext. Use: N/A
Rx: N/A
HPN: TINC.

First approval date: 09/01/2008
Last update date: 10/01/2012

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ECHINACEA **3212** **ECHN**

NAME IN CONTEMPORARY USE:
1) Echinacea angustifolia DC
2) Echinacea pallida (Nutt.) Nutt.

SYNONYMS:

Latin: Rudbeckia angustifolia L., Rudbeckia pallida Nutt.

English: Coneflower, Black Sampson, Pale Purple Coneflower, Echinacea

Spanish:

French:

German: Schmalblättrige Kegelblume

Italian:

BIOLOGICAL CLASSIFICATION: Family Asteraceae (Sunflower Family)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
The leaves develop a faintly aromatic odor when crushed, and have a slightly aromatic taste and bitter aftertaste. The flower heads have an aromatic odor and an aromatic, lingeringly hot, slightly astringent taste. Both plants have a characteristic allelopathic root system with a 30 to 50 cm long, reddish-brown to ochre-colored, strong taproot, with numerous finely-branched side roots.
Echinacea angustifolia: The upright, simple or branched, single-headed, roughly hairy stem grows to a height of 25 to 60 cm, occasionally up to 90 cm, and is increasingly thickened in its upper third, and distinctly so under the flower head. The usually long-stalked basal leaves are 12 to 27 cm long, with an elliptical to lanceolate lamina that is 10 to 40 mm wide, three-veined, entire, blue-green to dark green, and warty and rough-haired on both sides. The lower stem leaves are 6 to 15 cm long, 10 to 35 mm wide, and long-stalked; the upper stem leaves are short-stalked to sessile and pointed.
When fully open, the capitular flower heads are 9 to 16 cm wide and surrounded by three to four rings of 6-11 mm long, 2 -3 mm wide, entire, lanceolate sepals, which are also densely warty and rough-haired. The inflorescence base is initially flat, later conically arching, up to 25 mm wide and up to 30 mm high. It bears numerous dark red, keel-shaped, compressed, chaff-like bracts, the tips of which reach approximately to the upper edge of the corolla tube of the disk floret.
The 14 to 20 marginal, usually sterile ray florets have a three-pointed corolla up to 35 mm long and 5 to 8 mm wide, which is widest in the top third. The corolla is pink to light purple and initially upright, before starting to droop soon after the beginning of flowering. The five-tipped, hermaphroditic disk florets are greenish. The anthers of the five stamens are fused into a tube. The calyx is reduced to a slightly wavy border, apart from four longer teeth extending from the corners. The ovary is four-edged and laterally compressed.
Echinacea pallida: The upright, usually unbranched stem grows to a height of 40 to 95 cm, occasionally up to 1.2 m, and is sparsely hairy towards the base, and thickly hairy higher up. The basal leaves are up to 30 cm long, and have an elongated, lanceolate to elongated elliptical, entire, dark to blue-green, three-veined lamina up to 16 cm long and 20 to 45 mm wide, which is rough on both sides and on the margin due to the presence of white bristles up to 1 mm long. The 8 to 14 cm long petiole ends in a leaf sheath up to 25 mm long. The lower stem leaves are 15 to 38 cm long and 15 to 45 mm wide, and have a petiole that is 10 to 25 cm long and 10 to 25 mm wide. The lamina of the stem leaves is pointed, with thickening in the region where it joins the petiole. Towards the top, the stem leaves have shorter petioles; the uppermost are sessile.
When fully open, the flower heads are 11 to 20 cm wide, with a strongly arched, almost hemispherical inflorescence base 45 to 50 mm wide and 40 mm high. The sepals are lanceolate to narrowly lanceolate, arranged in three to four rows, and are 8 to 17 mm long, 2 to 4 mm wide, hairy and ciliate at the margin. The inflorescence base bears numerous, 10 to 13 mm long, purple-colored, keel-like, chaff-

like bracts, pointed at the front, which extend 3 mm beyond the disk florets.
The sterile, marginal ray florets have a 3 to 8 cm long, 4 to 8 mm wide corolla, which droops sharply downward soon after the beginning of flowering. It is pink to purple or light violet in color, and three-tipped. The five-tipped, hermaphroditic disk florets are purplish-brown to dark red in color, and 8 to 10 mm long. The corolla tips are 2 to 3 mm long. The calyx has four longish teeth emerging at the corners, otherwise it is reduced to a finely-dentate border.

RANGE AND HABITAT:
Native to the prairie regions of America. Widely cultivated.

PREPARATION AND CLASSIFICATION:
Tincture of the whole plant (Class C or Class N).

MEDICATION:
OTC: TINC.
Ext. Use: TINC.
Rx: N/A
HPN: N/A

First approval date: 07/01/2008
Last update date: 09/17/2009

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FERRUM PHOSPHORICUM 3431 FEPH

NAME IN CONTEMPORARY USE: Ferrous phosphate BPC 73

SYNONYMS:

Latin:

English: Ferri phosphas USP 1860, Ferrosoferric phosphate

Spanish:

French: Phosphate ferrosoferrique

German: Eisen(II)-phosphat

Italian:

BIOLOGICAL CLASSIFICATION:

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
A bluish-gray powder, odorless and tasteless. Insoluble in water or alcohol; soluble in hydrochloric acid, forming a yellow solution, which gives a dark-blue precipitate with the ferro- or ferricyanide of potassium. With barium chloride a slight turbidity is noticed, but the solution shows no change when treated with hydrogen sulfide. No precipitate is thrown down when sufficient tartaric acid is added to the acid solution and an excess of ammonia. The powder has a greenish-gray color when warmed, or grayish-brown at a higher temperature. The filtrate obtained after boiling it with caustic soda gives, when neutralized, a yellow precipitate with nitrate of silver. On treating the powder with hot distilled water and heating it on platinum foil, it should evaporate without residue. This salt is obtained by mixing the solutions of sulfate of iron, and phosphate and acetate of sodium, and then washing and drying the resulting precipitate. This should not be confounded with the ferri phosphas of the U.S.P. 1890, which salt comes in thin, bright green, transparent scales.

RANGE AND HABITAT:

PREPARATION AND CLASSIFICATION:
Trituration (Class F). Liquid attenuation (Class H): 8x and higher.

MEDICATION:
OTC: 1X
Ext. Use: 1X
Rx: N/A
HPN: N/A

First approval date: 12/01/2001
Last update date: 11/11/2011

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GALPHIMIA GLAUCA **4015** **GALP**

NAME IN CONTEMPORARY USE: ***Galphimia glauca* Cav.**

SYNONYMS:

Latin: *Thryallis glauca* Kuntze

English: Golden thryallis, Gold shower, Shower of gold, Rain of gold

Spanish: Calderona amarilla, Palo del muerto

French: Réséda, Pluie d'or, Gerbe d'or

German: Kleiner Goldregen

Italian:

BIOLOGICAL CLASSIFICATION: Family Malpighiaceae (Malpighia Family)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
A shrub, about 1.8 m high, with opposite leaves, without glands at the base of a 4-12 mm long petiole, which is grooved along the upper side and very occasionally covered with dark red downy hairs. The leaves are up to 60 mm long and 30 mm wide, ovate or elongated ovate, obtuse or rounded at the base and often pointed at the apex. The upper surface is wrinkled to smooth, glabrous and usually greenish-gray, the underside lighter in color and rough in appearance, with a prominent whitish midrib and less distinct lateral veins. The margin is slightly thickened, entire and downturned, particularly on the lower part. On either side of the leaf or slightly above it is a shallowly infundibulate brownish to black gland up to 1 mm in diameter on a pedicel about 0.5 mm long. The composite racemose inflorescence is up to 120 mm long and contains 10-30 slightly zygomorphic golden yellow to yellowish-brown flowers. The inflorescences are glabrous or covered with dark red hairs. The pedicels are 6-11 mm long and subtended by a linear-lanceolate to linear, often reddish-brown bract, with a pair of linear-lanceolate, reddish-brown bracteoles 1-4 mm in length situated in the region from slightly above the base to just below halfway up. The flowers are up to 23 mm wide and often spread out flat. The calyx consists of five obovate to elongated-ovate, green sepals that are 3-4 mm long, slightly lighter in color at the margin, with the apex slightly reflexed. The five varyingly large petals are up to 9 mm long and 4-5 mm wide, with finely fringed margins, and carinate on the underside. Basally they are obtuse and almost cordate, or ovate and slightly narrowed. The claw is 1.5-2 mm long and often tinged red, on the inside at least. The lower parts of the petals are also occasionally tinged red. The filaments of the ten stamens are reddish to brown. The trilocular superior ovary is a flattened sphere, with the dorsum distinctly carinate. The carpels are dark green to greenish, occasionally reddish-violet in the region of the keel, and each terminate in a pistil.

RANGE AND HABITAT:
Native from Mexico to Panama; naturalized in the West Indies. Cultivated in Europe in greenhouses.

PREPARATION AND CLASSIFICATION:
Tincture of the leaves and blossoms (Class C).

MEDICATION: **OTC:** TINC.
Ext. Use: N/A
Rx: N/A
HPN: N/A

First approval date: 04/30/2012
Last update date: 06/20/2012

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GLONOINUM **4038** **GLON**

NAME IN CONTEMPORARY USE: Nitroglycerin

SYNONYMS:

Latin: Trinitrinum

English: Glyceryl trinitrate, Glonoin, Trinitrin

Spanish:

French: Trinitrine, Glonoïne, Nitroglycérine

German: Nitroglyzerin, Trinitroglyzerin

Italian:

BIOLOGICAL CLASSIFICATION:

CHEMICAL FORMULA AND MOLECULAR WEIGHT: $C_3H_5N_3O_9$ 227.09

DESCRIPTION:
The pure substance is a pale yellow, odorless, oily liquid, with a sweet burning taste; specific gravity: 1.6. It explodes on rapid heating or on percussion. One gram dissolves in 800 ml of water, in 4 g of alcohol. It is extremely poisonous, and the inhalation of its vapors causes prostration and severe aching in the head. The solutions should be stored in a cool place in airtight containers and protected from light; they should be dispensed in glass containers with suitable metal closures. The pure substance is highly unstable and should be treated as an explosive, hazardous material.
The HPUS starting material is Diluted Nitroglycerin USP. Diluted Nitroglycerin USP is a clear, almost colorless liquid, containing not less than 90% and not more than 110% w/w of the labeled amount of nitroglycerin ($C_3H_5N_3O_9$). The starting material is miscible with water and alcohol.

RANGE AND HABITAT:

PREPARATION AND CLASSIFICATION:
Solution 1/100 in strong alcohol (Class B).

MEDICATION:

OTC: 6X
Ext. Use: N/A
Rx: 4X
HPN: 2X

First approval date: 11/01/2010
Last update date: 12/16/2010

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HEPAR SULPHURIS CALCAREUM 4232 HEPS

NAME IN CONTEMPORARY USE: Crude calcium sulfide

SYNONYMS:

Latin: Hepar sulphuris, Calcium sulphuratum hahnemanni

English: Impure calcium sulfide, Liver of sulfur

Spanish:

French: Foie de soufre calcaire

German: Kalkschwefelleber

Italian:

BIOLOGICAL CLASSIFICATION:

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
White to gray, porous masses, or a white or yellowish to pale-gray amorphous powder, with the odor of hydrogen sulfide and an unpleasant, alkaline taste. Is insoluble in water or alcohol; soluble in dilute hydrochloric acid with the evolution of hydrogen sulfide.
Hahnemann's directions for preparing the starting material were: mix equal parts of clean and finely powdered oystershells and well-mashed flowers of sulfur, place them in a hermetically-closed clay crucible, and keep the mixture at a white heat for at least ten minutes. The product is to be cooled and preserved in glass-stoppered bottles, protected from the light.
The following can also be used to produce a more consistent starting material: mix together equal parts of sulfur and Calcium carbonicum Hahnemanni and triturate thoroughly. Fill a porcelain crucible (upper diameter about 70 mm) almost to the rim with this mixture, using a pestle to tamp the solid down, then cover the crucible with a porcelain lid and place in a preheated oven. Calcine at 1,100 to 1,150 °C for 1 hour, cool, and then grind to a powder (180 µm, U.S. Standard No. 80).

RANGE AND HABITAT:

PREPARATION AND CLASSIFICATION:
Trituration (Class F).
Liquid attenuation (Class H): 8X and higher.

MEDICATION:

OTC: 1X

Ext. Use: 1X

Rx: N/A

HPN: N/A

First approval date: 06/01/2010
Last update date: 10/18/2010

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HISTAMINUM HYDROCHLORICUM 4275 HIHY

NAME IN CONTEMPORARY USE: **Histamine dihydrochloride**

SYNONYMS:

Latin: Histaminum muriaticum
English: Histamine hydrochloride, Histamine bi-chlorhydrate
Spanish:
French: Chlorhydrate d'histamine
German: Histaminhydrochlorid
Italian:

BIOLOGICAL CLASSIFICATION:

CHEMICAL FORMULA AND MOLECULAR WEIGHT: $C_5H_9N_3 \cdot 2HCl$ 184.07

DESCRIPTION:
Odorless, hygroscopic, colorless crystals, or white or almost white crystalline powder, with an acid, salty taste. Very soluble in water and methanol; soluble in alcohol and acetone; practically insoluble in chloroform and ethyl ether.

RANGE AND HABITAT:

PREPARATION AND CLASSIFICATION:
Solution 1/10 in dispensing alcohol (Class A).
Trituration (Class F).

MEDICATION:
OTC: 4X
Ext. Use: N/A
Rx: 1X
HPN: N/A

First approval date: 11/01/2012
Last update date: 12/07/2012

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IRIS VERSICOLOR **4447** **IRSV**

NAME IN CONTEMPORARY USE: ***Iris versicolor* L.**

SYNONYMS:

Latin:

English: Blue flag, Wild iris, Flag lily

Spanish:

French: Glaïeul bleu, Iris

German: Buntfarbige Schwertlilie, Iris

Italian:

BIOLOGICAL CLASSIFICATION: Family Iridaceae (Iris Family)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
A perennial herb with solid stems 20-90 cm high. Leaves are green to grayish-green, often purplish basally, prominently veined, 30-45 cm long and 1-3 cm wide, blade linear-lanceolate. Inflorescences are compact, 2-4-flowered; spathes never foliaceous, 3-6 cm, unequal, outer shorter than inner, margins shiny, darker in color. Perianth violet-blue to rarely white; floral tube funnelform, constricted above ovary, 1-1.2 cm; sepals ovate to reniform, base abruptly attenuate, signal a pubescent, greenish or greenish yellow patch surrounded by heavily veined purple on white at base of blade; petals lanceolate to oblong-lanceolate, much shorter than sepals, firm; ovary rounded-triangular in cross section, somewhat inflated, 0.8-2 cm; style 3-3.5 cm, base not auriculate, margins entire or toothed, crests reflexed, 0.7-1.5 cm; stigmas unlobed, triangular or rounded-triangular, margins entire; pedicel 2-8 cm, frequently exceeding spathe. Capsules often persistent over winter, ovoid to oblong-ellipsoid, conspicuously beaked, obtusely triangular in cross section, 1.5-6 cm, tardily dehiscent. Seeds dark brown, D-shaped, 5-8 mm, shiny, thin, hard. The thick, branched, creeping rhizome may be more than 200 mm long and up to 15 mm thick and divided into distinct segments. The upper and lower sides are flattened and appear annular due to scars left by the leaves of earlier years. The upper side shows fibrous residues of old, withered leaves, the underside numerous long, yellowish white fibrous roots growing in transverse rows; on the older parts of the rhizome the sites where roots were formerly attached remain as scars. The tip is matted with residues of the previous year's leaves. The rhizome is yellowish to brownish on the outside, sometimes also tinged green, and white, yellowish or a variable shade of pink on the inside. Beneath the dark epidermis lies a white cortex that is bounded by the endodermis. The yellowish ground tissue of the central cylinder contains numerous, generally leptocentric, vascular bundles that are visible on the cut surface as scattered dark spots.

RANGE AND HABITAT:
Europe, northern Africa, northern India, general in the United States; found in wet places.

PREPARATION AND CLASSIFICATION:
Tincture of the rhizome (Class C or Class N).

MEDICATION:
OTC: TINC.
Ext. Use: TINC.
Rx: N/A
HPN: N/A

First approval date: 04/30/2012
Last update date: 06/21/2012

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LEDUM PALUSTRE **5448** **LEDM**

NAME IN CONTEMPORARY USE: ***Ledum palustre* L.**

SYNONYMS:

Latin: *Ledum decumbens* Lodd., *Ledum groenlandicum* Oeder

English: Wild rosemary, Marsh cistus, Marsh tea, Silesian rosemary

Spanish:

French: Romarin sauvage, Lédon des marais

German: Sumpfporst

Italian:

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BIOLOGICAL CLASSIFICATION: Family Ericaceae (Heath Family)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
An evergreen shrub with stem 0.6-0.9 m high. The bark of the stem is ash-colored. The leaves are alternate, short-petioled or sessile, linear-lanceolate or linear, 5 cm long, 8-12 mm broad, tough and leathery, with margins inrolled downwards. The upper surface of the leaf is green, glabrous and shining, while the lower surface is densely covered with rust-colored down. The central vein of the leaf projects markedly on the underside and is depressed on the upper surface. The young shoots show little lignification and are invested with a dense felt of hair; older shoots show marked lignification and are green or brownish-green. The shoots terminate occasionally in an inflorescence, but generally in a slightly acuminate, broadly elliptical bud that is about 1 cm in length and invested with numerous greenish or greenish-brown bud scales arranged like roof tiles. The numerous white or pale rose-red flowers appear in dense terminal corymbs with filiform, pubescent pedicels. The whole plant has a heavy, aromatic odor, and a camphoraceous, bitter taste.

RANGE AND HABITAT:
Northern Europe, Asia, Newfoundland, Labrador to Alaska and Aleutian Islands; found in bogs.

PREPARATION AND CLASSIFICATION:
Tincture of the leafy twigs (Class C).

MEDICATION:
OTC: 4X
Ext. Use: 2X
Rx: 2X
HPN: TINC.

First approval date: 08/01/2012
Last update date: 08/08/2012

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NATRUM MURIATICUM **6433** **NAMU**

NAME IN CONTEMPORARY USE: Sodium chloride

SYNONYMS:

Latin: Natrii chloridum
English: Salt
Spanish:
French: Chlorure de sodium, Sel
German: Natriumchlorid, Salz
Italian:

BIOLOGICAL CLASSIFICATION:

CHEMICAL FORMULA AND MOLECULAR WEIGHT: NaCl 58.45

DESCRIPTION:
Cubic, white crystals, granules, or powder; colorless and transparent or translucent when in large crystals; with a well-known saline taste. The salt of commerce usually contains some calcium and magnesium chlorides which absorb moisture. Heated it crepitates, melts at 804 °C, and begins to volatilize at a little above this temperature. It is freely soluble in water and very slightly soluble in alcohol.

RANGE AND HABITAT:

PREPARATION AND CLASSIFICATION:
Solution 1/10 in water (Class A).
Trituration (Class F).

MEDICATION:
OTC: 1X
Ext. Use: 1X
Rx: N/A
HPN: N/A

First approval date: 11/01/2010
Last update date: 12/21/2010

HPUS
HOMOEOPATHIC PHARMACOPOEIA of the United States

The Homœopathic Pharmacopœia of the United States

Welcome Ron Marron

Monograph

SANGUINARIA CANADENSIS **8033** **SNGC**

NAME IN CONTEMPORARY USE: ***Sanguinaria canadensis* L.**

SYNONYMS:

Latin: *Sanguinaria grandiflora* Rosc., *Sanguinaria acaulis* Moench.,*Sanguinaria vernalis* Salisb.

English: Bloodroot, Sanguinaria

Spanish:

French: Sanguinaire du Canada

German: Kanadische Blutwurzel

Italian:

BIOLOGICAL CLASSIFICATION: Family Papaveraceae (Poppy Family)

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
A perennial, acaulescent herb, with a red, cylindrical, prostrate rhizome, 5-10 cm long, 6-19 mm thick, slightly-branched, with fibrous roots beneath, and having an abundant, reddish-orange, acrid juice. The leaves, arising from each bud of the rhizome, are five to nine palmately-lobed on long reddish-orange colored petioles, glabrous, pale green above, bluish-white beneath, with orange colored veins, and not attaining full growth until the flowers have fallen. The handsome, white flowers, 2.5-3.8 cm in diameter, appear in April and May on a one-flowered, naked scape, 15 cm high, the bud erect, the petals usually eight, not crumpled.
The rhizome has a faint odor. The distinctly annulated, rugose pieces are up to 100 mm long, sometimes over 10 mm thick, and reddish-brown on the outside. They frequently carry residues of numerous short, thin, brittle roots or marks left where they have broken off. The often highly shriveled pieces are hard and twisted, unevenly compressed and usually unbranched. The fracture is smooth, the fracture surface whitish to a pale brownish white, with indistinct reddish zones in places. Under a magnifying glass, the entire surface is scattered with numerous glossy red dots, sometimes appearing dark reddish-brown all over.

RANGE AND HABITAT:
United States and Canada; common in open rich woods and along shaded streams.

PREPARATION AND CLASSIFICATION:
Tincture of the rhizome and roots (Class C).

MEDICATION:
OTC: 3X
Ext. Use: 3X
Rx: TINC.
HPN: N/A

First approval date: 05/01/2009
Last update date: 09/24/2012

The Homœopathic Pharmacopœia of the United States

SULPHUR **8155** **SULF**

NAME IN CONTEMPORARY USE: Sublimed sulfur

SYNONYMS:

Latin: Sulphur sublimatum
English:
Spanish:
French: Soufre sublimé
German: Sublimierter Schwefel
Italian:

BIOLOGICAL CLASSIFICATION:

CHEMICAL FORMULA AND MOLECULAR WEIGHT: S 32.06

DESCRIPTION:
A fine, yellow, crystalline powder, having a faint odor and taste. Is practically insoluble in water; sparingly soluble in olive oil; and practically insoluble in alcohol. It burns in the air forming sulfur dioxide, which can be recognized by its characteristic odor. Sublimed sulfur, dried over phosphorous pentoxide for 4 hours, contains not less than 99.5% and not more than 100.5% of sulfur.

RANGE AND HABITAT:

PREPARATION AND CLASSIFICATION:
Solution 1/10,000 in strong alcohol (Class B).
Trituration (Class F).

MEDICATION:
OTC: 1X
Ext. Use: 1X
Rx: N/A
HPN: N/A

First approval date: 06/01/2010
Last update date: 10/18/2010

HPUS
HOMOEOPATHIC PHARMACOPOEIA of the United States

The Homœopathic Pharmacopœia of the United States

Welcome Ron Marron

Monograph

SULPHUR IODATUM **8156** **SUIO**

NAME IN CONTEMPORARY USE: **Sulfur iodide**

SYNONYMS:

Latin: Flavum iodatum
English: Iodosulfane
Spanish:
French: Sulfure d'iode, Iodure de soufre
German: Schwefeljodat, Jodschwefel
Italian:

BIOLOGICAL CLASSIFICATION:

CHEMICAL FORMULA AND MOLECULAR WEIGHT:

DESCRIPTION:
A grayish-black mass of metallic luster and iodine odor. Exposed to air, it loses iodine. Is almost insoluble in water, but freely soluble in carbon disulfide; slightly soluble in alcohol. Potassium iodide solution dissolves its iodine leaving free sulfur. Sulfur iodide is obtained by fusing together 4 parts of iodine with 1 part of sulfur. The commercial product contains free iodine as well as free sulfur in small amounts.

RANGE AND HABITAT:

PREPARATION AND CLASSIFICATION:
Solution 1/1000 in strong alcohol (Class B).
Trituration (Class F).

MEDICATION:
OTC: 3X
Ext. Use: N/A
Rx: 1X
HPN: N/A

First approval date: 09/01/2008
Last update date: 10/04/2012

EXHIBIT 6

Third Amended Complaint

Allen, et al. v. Hyland's, Inc., et al.
Case No.: 12-cv-1150-DMG (MAN)

Saved 2.3.12

Law Offices of
Ronald A. Marron
A Professional Law Corporation

3636 Fourth Avenue, Ste 202
San Diego, CA 92103

Tel: 619.696.9006
Fax: 619.564.6665

February 3, 2012

Via: Certified Mail, (receipt acknowledgment with signature requested

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

RE: NOTICE: Violations of the California Consumer Legal Remedies Act and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this letter constitutes notice under the California Consumer Legal Remedies Act, ("CLRA"), California Civil Code Section 1750, *et seq.*, (the "ACT") — pursuant specifically to Civil Code Section 1782 — notifying **HYLAND's and STANDARD HOMEOPATHIC COMPANY** ("YOU" and "YOUR") of violations of the Act and of our demand that YOU remedy such violations within thirty (30) days from your receipt of this letter.

This firm represents Kim Allen, who purchased several products YOU distribute in California and elsewhere. For example, Ms. Allen purchased Hyland's Calms Forte. Ms. Allen was exposed to and saw YOUR claims about the product, purchased the product in reliance on those claims, and suffered injury in fact as a result of YOUR false and misleading advertising.

YOU falsely market YOUR products by putting false and misleading claims on the labels. For example, YOU advertise Calms Forte as a sleep aid product, with an image of a moon in a bedtime hat, and that Calms Forte provides "relief of simple nervous tension and occasional sleeplessness." In fact, the Calms Forte does neither. The claims on the label of Calms Forte also include statements such as "sleep aid," "for restless or wakeful sleep from exhaustion," "for stress, nervousness or nervous headache," "for drowsiness with incomplete sleep," "for nervous irritability," "biochemic phosphates for enhancing cellular function," among other representations. The purported

active ingredients in this product are Avena Sativa 1X Double Strength, Humulus Lupulus 1X Double Strength, Chamomilla 2X (Chamomile), and the assorted biochemic phosphates that purportedly enhance cellular function are Calcarea Phosphorica, Ferrum Phosphoricum, Kali Phosphoricum, Natrum Phosphoricum, and Magnesia Phosphoricum.

In summary, YOU claim that YOUR products contain active ingredients that will alleviate the symptoms indicated above. In fact, even if YOUR products contain the purportedly active ingredients as listed above, those ingredients are so greatly diluted as to be non-existent in the product, such that the product is ineffective for its intended uses. Further, YOUR products are essentially sugar pills with no efficacy beyond a placebo.

A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding your products or services.

In conclusion, YOUR material misrepresentations are deceiving customers into purchasing YOUR products under the representation that they provide significant health benefits, when in fact they do not.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices in violation of the CLRA include, but are not necessarily limited to:

§ 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.

§ 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

§ 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

YOU have failed to honor your consumer protection obligations. Based upon the above, demand is hereby made that YOU conduct a corrective advertising campaign and destroy all misleading and deceptive advertising materials and products.

Please be advised that your failure to comply with this request within thirty (30) days may subject you to the following remedies, available for violations of the CLRA, which will be requested in the first amended class action complaint on behalf of our client, Ms. Kim Allen, and all other similarly-situated California and U.S. residents:

(1) The actual damages suffered;

(2) An order enjoining you for such methods, acts or practices;

(3) Restitution of property (when applicable);

(4) Punitive damages;

(5) Any other relief which the court deems proper; and

(6) Court costs and attorneys' fees.

Additionally, I remind you of your legal duty to preserve all records relevant to such litigation. See, e.g., *Convolve, Inc. v. Compaq Computer Corp.*, 223 F.R.D 162, 175 (S.D.N.Y 2004); *Computer Ass'n Int'l v. American Fundware, Inc.*, 133 F.R.D. 166, 168-69 (D. Colo. 1990). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that related to the formulation and marketing of YOUR products will be sought in the forthcoming discovery process. You therefore must inform any employees, contractors, and third-party agents (for example product consultants and advertising agencies handling your product account) to preserve all such relevant information.

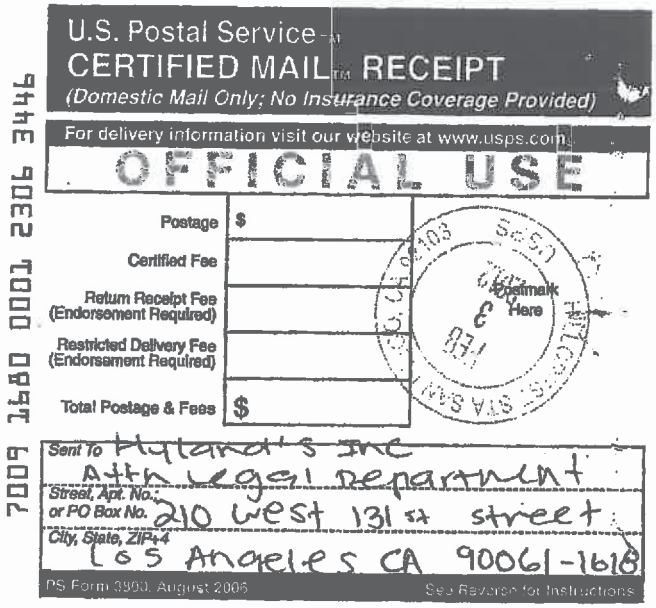
In addition, California Civil Code Section 1780 (b) provides in part that: "Any consumer who is a **senior citizen or a disabled person,** as defined in subdivision (f) and (g) of Section 1761, as part of an action under subdivision (a), may seek and be awarded, in addition to the remedied specified therein, up to **five thousand dollars** ($5,000)... [emphasis added]".

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

Sincerely,

THE LAW OFFICES OF RONALD A. MARRON APLC

/s/ Ronald A. Marron
Ronald A. Marron
Attorney for Kim Allen,
and all others similarly situated


U.S. Postal Service
CERTIFIED MAIL™ RECEIPT
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For delivery information visit our website at www.usps.com
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Certified Fee
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Restricted Delivery Fee (Endorsement Required)
Total Postage & Fees $
Postmark Here
7009 1680 0001 2306 3446
Sent To Hytarat's Inc
Attn Legal Department
Street, Apt. No.; or PO Box No. 210 West 131st street
City, State, ZIP+4 Los Angeles CA 90061-1618
PS Form 3800, August 2006 See Reverse for Instructions

Law Offices of
Ronald A. Marron
A Professional Law Corporation

› Fourth Avenue, Ste 202
San Diego, CA 92103

Tel: 619.696.9006
Fax: 619.564.6665

February 15, 2012

Via: Certified Mail, (receipt acknowledgment with signature requested

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

RE: NOTICE: Violations of the California Consumer Legal Remedies Act and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this letter constitutes notice under the California Consumer Legal Remedies Act, ("CLRA"), California Civil Code Section 1750, *et seq.*, (the "ACT") — pursuant specifically to Civil Code Section 1782 — notifying **HYLAND's and STANDARD HOMEOPATHIC COMPANY** ("YOU" and "YOUR") of violations of the Act and of our demand that YOU remedy such violations within thirty (30) days from your receipt of this letter.

This firm represents Daniele Xenos, who purchased several products YOU distribute in California and elsewhere. For example, Ms. Xenos purchased Hyland's Calms Forte, Baby Teething Tablets, Migraine Headache Relief, ClearAc and Poison Ivy/Oak Tablets. Ms. Xenos was exposed to and saw YOUR claims about the products, purchased the products in reliance on those claims, and suffered injury in fact as a result of YOUR false and misleading advertising.

YOU falsely market YOUR products by putting false and misleading claims on the labels. For example, YOU advertise Calms Forte as a sleep aid product, with an image of a moon in a bedtime hat, and that Calms Forte provides "relief of simple nervous tension and occasional sleeplessness." In fact, the Calms Forte does neither. The claims on the label of Calms Forte also include statements such as "sleep aid," "for restless or wakeful sleep from exhaustion," "for stress, nervousness or nervous headache," "for drowsiness with incomplete sleep," "for nervous irritability," "biochemic

phosphates for enhancing cellular function," among other representations. The purported active ingredients in this product are *Avena Sativa 1X Double Strength, Humulus Lupulus 1X Double Strength, Chamomilla 2X* (Chamomile), *Calcarea Phosphorica, Ferrum Phosphoricum, Kali Phosphoricum, Natrum Phosphoricum, and Magnesia Phosphoricum.*

YOU advertise that Hyland's Baby Teething Tablets "provide a natural, homeopathic formula for symptoms of simple restlessness and wakeful irritability due to the cutting of teeth." The product's label includes the following statements: "Relieve Pain and Irritability from Teething," "Soft tablets dissolve instantly," "100% natural," among other representations. The purported active ingredients in this product are *Calcarea Phosphorica* (6x HPUS), *Chamomilla Recutita* (Chamomile) (6 HPUS), *Coffee Cruda* (6x HPUS), *Belladonna* (12x HPUS)

Further, YOU advertise on its label and elsewhere that Hyland's Migraine Headache Relief is a natural remedy for migraines, that "works fast to relieve migraine headache pain without aspirin, caffeine or sedatives" and that the product "relieves pressure, throbbing and light and noise sensitivity associated with migraines." One of your product packaging depicts a happy, smiling woman. The label includes statements such as: "100% Natural," "Migraine Headache Relief," "Quick Dissolving tablets," "Aspirin free," among other representations. The purported active ingredients in this product are: *Glonoinum* 12X HPUS, *Belladonna* 6X HPUS, *Gelsemium* 6X HPUS, *Nux Vomica* 6X HPUS, *Iris Versicolor* 6X HPUS and *Sanguinaria Canadensis* 6X HPUS.

Further, YOU represent that Hyland's ClearAc is designed to manage and provide symptomatic relief of symptoms of pimples, blackheads and blemishes associated with common acne. Specifically, the product's label include statements such as: "Natural Treatment for Pimples, Acne, Blackheads, and Oily Skin," "Medicated Skin Cleanser" "Gentle on Skin No Harsh Chemicals," "Hyland's 100% Natural ClearAc Acne Tablets," "No Messy Makeup, " among other representations. The purported active ingredients in this product are: *Echinacea Ang.* 6X HPUS, *Berberis Vulg.* 6X HPUS, *Sulphur Iod* 6X HPUS and *Hepar Sulph* 6X HPUS.

Lastly, YOU represent that Hyland's Poison Ivy/Oak Tablets relieve the symptoms experienced after coming in contact with poison ivy or oak, such as skin break outs, itching, burning and blisters. Specifically, YOU claim on the product's label that the product is a "Natural Relief for Itching, Burning and Crusting Skin Due to Exposure to Poison Ivy or Oak," among other representations. The purported active ingredients in this product are: *Rhus Toxicodendron* 6X HPUS, *Croton Tiglium* 6X HPU and Xerophyllum 6X HPUS.

In summary, YOU claim that YOUR products contain active ingredients that will alleviate the symptoms indicated above. In fact, even if YOUR products contain the purportedly active ingredients as listed above, those ingredients are so greatly diluted as to be non-existent in the products, such that the products are ineffective for their intended uses. Further, YOUR products are essentially sugar pills with no efficacy beyond a placebo.

A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding your products or services.

In conclusion, YOUR material misrepresentations are deceiving customers into purchasing YOUR products under the representation that they provide significant health benefits, when in fact they do not.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices in violation of the CLRA include, but are not necessarily limited to:

§ 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.

§ 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

§ 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

YOU have failed to honor your consumer protection obligations. Based upon the above, demand is hereby made that YOU conduct a corrective advertising campaign and destroy all misleading and deceptive advertising materials and products.

Please be advised that your failure to comply with this request within thirty (30) days may subject you to the following remedies, available for violations of the CLRA, which will be requested in the first amended class action complaint on behalf of our client, Ms. Daniele Xenos, and all other similarly-situated U.S. residents:

(1) The actual damages suffered;

(2) An order enjoining you for such methods, acts or practices;

(3) Restitution of property (when applicable);

(4) Punitive damages;

(5) Any other relief which the court deems proper; and

(6) Court costs and attorneys' fees.

Additionally, I remind you of your legal duty to preserve all records relevant to such litigation. See, e.g., *Convolve, Inc. v. Compaq Computer Corp.*, 223 F.R.D 162, 175 (S.D.N.Y 2004); *Computer Ass'n Int'l v. American Fundware, Inc.*, 133 F.R.D. 166, 168-69 (D. Colo. 1990). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that related to the formulation and marketing of YOUR products will be sought in the forthcoming discovery process. You therefore must inform any employees, contractors, and third-party agents (for example product consultants and advertising agencies handling your product account) to preserve all such relevant information.

In addition, California Civil Code Section 1780 (b) provides in part that: "Any consumer who is a **senior citizen or a disabled person**, as defined in subdivision (f) and (g) of Section 1761, as part of an action under subdivision (a), may seek and be awarded, in addition to the remedied specified therein, up to **five thousand dollars** ($5,000)... [emphasis added]".

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

Sincerely,

THE LAW OFFICES OF RONALD A. MARRON APLC

/s/ Ronald A. Marron
Ronald A. Marron
Attorney for Daniele Xenos,
and all others similarly situated

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) P. HIJOSA C. Date of Delivery 2-16-12

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7009 1680 0001 2306 3538

PS Form 3811, February 2004 Domestic Return Receipt 102595-M-1540

U.S. Postal Service
CERTIFIED MAIL™ RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

For delivery information visit our website at www.usps.com

OFFICIAL USE

Postage	$ 0.65	0932
Certified Fee	2.95	10
Return Receipt Fee (Endorsement Required)	2.30	Postmark Here FEB 15 2012
Restricted Delivery Fee (Endorsement Required)	0.00	
Total Postage & Fees	$ 5.95	02/15/2012

Sent To: Hyland's, Inc. Standard Homeopathic Company
Street, Apt. No., or PO Box No.: 210 West 131st Street
City, State, ZIP+4: Los Angeles, CA 90061-1618

PS Form 3800, August 2006 See Reverse for Instructions

7009 1680 0001 2306 3538

Law Offices of
Ronald A. Marron
A Professional Law Corporation

3636 Fourth Avenue, Ste 202
San Diego, CA 92103

Tel: 619.696.9009
Fax: 619.564.6665

March 7, 2012

Via: Certified Mail, (receipt acknowledgment with signature requested

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

RE: NOTICE: Violations of the California Consumer Legal Remedies Act and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this letter constitutes notice under the California Consumer Legal Remedies Act, ("CLRA"), California Civil Code Section 1750, *et seq.*, (the "ACT") — pursuant specifically to Civil Code Section 1782 — notifying **HYLAND's and STANDARD HOMEOPATHIC COMPANY** ("YOU" and "YOUR") of violations of the Act and of our demand that YOU remedy such violations within thirty (30) days from your receipt of this letter.

This firm represents Daniele Xenos, who purchased Hyland's Leg Cramp with Quinine PM, a homeopathic product YOU distribute in California and elsewhere. Ms. Xenos purchased Leg Cramps with Quinine on at least one occasion, from a drugstore located in Decatur, Georgia, or online. Ms. Xenos was exposed to and saw YOUR claims about the product, purchased the product in reliance on those claims, and suffered injury in fact as a result of YOUR false and misleading advertising.

YOU falsely market YOUR products by putting false and misleading claims on the labels. For example, YOU represent that Leg Cramps with Quinine "relieves pain and cramps in lower body, legs, feet and toes with accompanying nighttime sleeplessness," and that it "provides effective pain relief that helps [the consumer] fall asleep and get back to sleep at night." In fact, the Leg Cramps with Quinine does neither. YOU further advertise that Leg Cramps with Quinine is a "non-habit forming Pain Relief with Restful Sleep." The claims on the label of Leg Cramps with Quinine also include statements such as "Temporarily relieves the symptoms of pain and cramps in lower

body, legs, feet and toes with accompanying sleeplessness and disrupted sleep," among other representations. The purported active ingredients in this product include *Calcarea Carbonica* 12X HPUS, *Causticum* 12X HPUS, *Chamomilla* 6X HPUS, *Cinchona Officinalis* 3X HPUS, *Cuprum Metallicum* 12X HPUS, *Lycopodium* 12X HPUS, *Magnesia Phosphorica* 6X HPUS, *Rhus Toxicodendron* 6X HPUS, *Silicea* 12X and *Sulphur* 6X HPUS. In fact, even if YOUR product contains the purportedly active ingredients as listed above, those ingredients are so greatly diluted as to be non-existent in the product, such that the product is ineffective for its intended uses. Further, YOUR product is essentially a sugar pill with no efficacy beyond a placebo.

A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding your products or services.

In conclusion, YOUR material misrepresentations are deceiving customers into purchasing YOUR product under the representation that it provides significant health benefits, when in fact it does not.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices in violation of the CLRA include, but are not necessarily limited to:

§ 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.

§ 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

§ 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

YOU have failed to honor your consumer protection obligations. Based upon the above, demand is hereby made that YOU conduct a corrective advertising campaign and destroy all misleading and deceptive advertising materials and products.

Please be advised that your failure to comply with this request within thirty (30) days may subject YOU to the following remedies, available for violations of the CLRA, which will be requested in the first amended class action complaint on behalf of our client, Ms. Daniele Xenos, and all other similarly-situated U.S. residents:

(1) The actual damages suffered;

(2) An order enjoining you for such methods, acts or practices;

(3) Restitution of property (when applicable);

(4) Punitive damages;

(5) Any other relief which the court deems proper; and

(6) Court costs and attorneys' fees.

Additionally, I remind you of your legal duty to preserve all records relevant to such litigation. See, e.g., *Convolve, Inc. v. Compaq Computer Corp.*, 223 F.R.D 162, 175 (S.D.N.Y 2004); *Computer Ass'n Int'l v. American Fundware, Inc.*, 133 F.R.D. 166, 168-69 (D. Colo. 1990). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that related to the formulation and marketing of YOUR products will be sought in the forthcoming discovery process. You therefore must inform any employees, contractors, and third-party agents (for example product consultants and advertising agencies handling your product account) to preserve all such relevant information.

In addition, California Civil Code Section 1780 (b) provides in part that: "Any consumer who is a **senior citizen or a disabled person**, as defined in subdivision (f) and (g) of Section 1761, as part of an action under subdivision (a), may seek and be awarded, in addition to the remedied specified therein, up to **five thousand dollars** ($5,000)… [emphasis added]".

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

Sincerely,

THE LAW OFFICES OF RONALD A. MARRON APLC

/s/ Ronald A. Marron
Ronald A. Marron
Attorney for Daniele Xenos,
and all others similarly situated

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Hyland's Inc
210 west 131st street
Los Angeles CA
90061-1618

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) C. Date of Delivery 3.8

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☐ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7009 1680 0001 2306 3682

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

U.S. Postal Service™
CERTIFIED MAIL™ RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

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Certified Fee
Return Receipt Fee (Endorsement Required)
Restricted Delivery Fee (Endorsement Required)
Total Postage & Fees $

MAR 07 2012
SAN DIEGO CA 92103

Postmark Here

Sent To Hyland's Inc
Street, Apt. No.; or PO Box No. 210 west 131st Street
City, State, ZIP+4 Los Angeles CA 90061-1618

PS Form 3800, August 2006 See Reverse for Instructions

7009 1680 0001 2306 3682

Law Offices of
Ronald A. Marron
A Professional Law Corporation
May 8, 2012

3636 Fourth Avenue, Ste 202
San Diego, CA 92103

Tel: 619.696.9006
Fax: 619.564.6665

Via: Certified Mail, (receipt acknowledgment with signature requested)

✓Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

Jeffrey Margulies
Joseph H. Park
Stephanie Stroup
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071

RE: NOTICE: Violations of the California Consumer Legal Remedies Act and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this letter constitutes notice under the California Consumer Legal Remedies Act, ("CLRA"), California Civil Code Section 1750, *et seq.*, (the "ACT") — pursuant specifically to Civil Code Section 1782 — notifying **HYLAND's and STANDARD HOMEOPATHIC COMPANY** ("YOU" and "YOUR") of violations of the Act and of our demand that YOU remedy such violations within thirty (30) days from your receipt of this letter.

This firm represents Sherrell Smith, who purchased homeopathic products YOU distribute in California and elsewhere. For example, Ms. Smith purchased Hyland's Leg Cramps product at Henry's (now doing business as Sprouts), located in Vista and Oceanside, California from approximately January 2009 through December 2011. Ms. Smith was exposed to and saw YOUR claims about the product, purchased the product in reliance on those claims, and suffered injury in fact as a result of YOUR false and misleading advertising.

In purchasing Hyland's Leg Cramp products, Plaintiff relied upon various representations and omissions Defendants made on the product's label and elsewhere.

YOU falsely market YOUR homeopathic products by putting false and misleading claims on the labels.

In fact, all of YOUR homeopathic products, not only Hyland's Leg Cramps product, are essentially sugar pills with no efficacy beyond a placebo. Even if YOUR

products contain the purportedly active ingredients, as listed on YOUR homeopathic products' labels, those ingredients are so greatly diluted as to be non-existent in the product, such that the product is ineffective for its intended uses. In addition, YOU omit the fact that YOUR statements about the products have not been evaluated by the FDA.

A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding your products or services.

In conclusion, YOUR material misrepresentations are deceiving customers into purchasing YOUR products under the representation that they provide significant health benefits, when in fact they do not.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices in violation of the CLRA include, but are not necessarily limited to:

§ 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.

§ 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

§ 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

YOU have failed to honor YOUR consumer protection obligations. Based upon the above, demand is hereby made that YOU conduct a corrective advertising campaign and destroy all misleading and deceptive advertising materials and products.

Please be advised that YOUR failure to comply with this request within thirty (30) days may subject YOU to the following remedies, available for violations of the CLRA, which will be requested in the amended class action complaint on behalf of our client, Ms. Smith, and all other similarly-situated California and U.S. residents:

(1) The actual damages suffered;

(2) An order enjoining you for such methods, acts or practices;

(3) Restitution of property (when applicable);

(4) Punitive damages;

(5) Any other relief which the court deems proper; and

(6) Court costs and attorneys' fees.

Additionally, I remind you of your legal duty to preserve all records relevant to such litigation. See, e.g., *Convolve, Inc. v. Compaq Computer Corp.*, 223 F.R.D 162, 175 (S.D.N.Y 2004); *Computer Ass'n Int'l v. American Fundware, Inc.*, 133 F.R.D. 166, 168-69 (D. Colo. 1990). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that related to the formulation and marketing of YOUR products will be sought in the forthcoming discovery process. You therefore must inform any employees, contractors, and third-party agents (for example product consultants and advertising agencies handling your product account) to preserve all such relevant information.

In addition, California Civil Code Section 1780 (b) provides in part that: "Any consumer who is **a senior citizen or a disabled person**, as defined in subdivision (f) and (g) of Section 1761, as part of an action under subdivision (a), may seek and be awarded, in addition to the remedied specified therein, up to **five thousand dollars** ($5,000)… [emphasis added]".

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

Sincerely,

THE LAW OFFICES OF RONALD A. MARRON APLC

/s/ Ronald A. Marron
Ronald A. Marron
Attorney for Sherrell Smith,
and all others similarly situated

U.S. Postal Service
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Restricted Delivery Fee (Endorsement Required)	0.00
Total Postage & Fees	$ 5.75

Postmark Here

05/02/2013

7009 1680 0001 2306 3590

Sent To: Hyland's, Inc. Standard Homeopathic Company
Street, Apt. No.; or PO Box No.: 210 West 131st Street
City, State, ZIP+4: Los Angeles, CA 90061-1619 (Smith)

PS Form 3800, August 2006 — See Reverse for Instructions

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

2. A
(
PS

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) | C. Date of Delivery 5/9

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

102595-02-M-1540

Law Offices of
Ronald A. Marron
A Professional Law Corporation
3636 Fourth Avenue, Ste 202
San Diego, CA 92103
Tel: 619.696.9006
Fax: 619.564.6665

May 8, 2012

Via: Certified Mail, (receipt acknowledgment with signature requested)

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

Jeffrey Margulies
Joseph H. Park
Stephanie Stroup
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071

RE: NOTICE: Violations of the California Consumer Legal Remedies Act and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this letter constitutes notice under the California Consumer Legal Remedies Act, ("CLRA"), California Civil Code Section 1750, *et seq.*, (the "ACT") — pursuant specifically to Civil Code Section 1782 — notifying **HYLAND's and STANDARD HOMEOPATHIC COMPANY** ("YOU" and "YOUR") of violations of the Act and of our demand that YOU remedy such violations within thirty (30) days from your receipt of this letter.

This firm represents Melissa Nigh, who purchased Hyland's teething products YOU distribute in California and elsewhere. Ms. Nigh was exposed to and saw YOUR claims about the products, purchased the Hyland's Teething products at the Target and Rite Aid stores in Morgan Hill, California from approximately 2005 to 2009 in reliance on those claims, and suffered injury in fact as a result of YOUR false and misleading advertising.

YOU falsely market YOUR products by putting false and misleading claims on the labels. For example, YOU advertise that Hyland's Baby Teething Tablets "provide a natural, homeopathic formula for symptoms of simple restlessness and wakeful irritability due to the cutting of teeth." The product's label includes the following statements: "Relieve Pain and Irritability from Teething," "Soft tablets dissolve instantly," "100% natural," among other representations. The purported active ingredients in this product are *Calcarea Phosphorica* (6x HPUS), *Chamomilla Recutita* (Chamomile) (6 HPUS), *Coffee Cruda* (6x HPUS), and *Belladonna* (12x HPUS).

In summary, YOU claim that YOUR products contain active ingredients that will alleviate the symptoms indicated above. In fact, even if YOUR products contain the purportedly active ingredients as listed above, those ingredients are ineffective and/or so greatly diluted as to be non-existent in the products, such that the products are ineffective for their intended uses. Further, YOUR products are essentially sugar pills with no efficacy beyond a placebo with trace ingredients that do not aid in the suggested remedial efficacy.

A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding YOUR products or services.

In conclusion, YOUR material misrepresentations are deceiving customers into purchasing YOUR products under the representation that they provide significant health benefits, when in fact they do not.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices in violation of the CLRA include, but are not necessarily limited to:

§ 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.

§ 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

§ 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

YOU have failed to honor your consumer protection obligations. Based upon the above, demand is hereby made that YOU conduct a corrective advertising campaign and destroy all misleading and deceptive advertising materials and products.

Please be advised that your failure to comply with this request within thirty (30) days may subject you to the following remedies, available for violations of the CLRA, which will be requested in the amended class action complaint on behalf of our client, Ms. Melissa Nigh, and all other similarly-situated California and U.S. residents:

(1) The actual damages suffered;

(2) An order enjoining you for such methods, acts or practices;

(3) Restitution of property (when applicable);

(4) Punitive damages;

(5) Any other relief which the court deems proper; and

(6) Court costs and attorneys' fees.

Additionally, I remind you of your legal duty to preserve all records relevant to such litigation. See, e.g., *Convolve, Inc. v. Compaq Computer Corp.*, 223 F.R.D 162, 175 (S.D.N.Y 2004); *Computer Ass'n Int'l v. American Fundware, Inc.*, 133 F.R.D. 166, 168-69 (D. Colo. 1990). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that related to the formulation and marketing of YOUR products will be sought in the forthcoming discovery process. You therefore must inform any employees, contractors, and third-party agents (for example product consultants and advertising agencies handling your product account) to preserve all such relevant information.

In addition, California Civil Code Section 1780 (b) provides in part that: "Any consumer who is a **senior citizen or a disabled person**, as defined in subdivision (f) and (g) of Section 1761, as part of an action under subdivision (a), may seek and be awarded, in addition to the remedied specified therein, up to **five thousand dollars** ($5,000)... [emphasis added]".

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

Sincerely,

THE LAW OFFICES OF RONALD A. MARRON APLC

/s/ Ronald A. Marron
Ronald A. Marron
Attorney for Melissa Nigh,
and all others similarly situated

U.S. Postal Service
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OFFICIAL USE

Postage	$
Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$ $5.73

Postmark Here

7009 1680 0001 2306 3606

Sent To: Hyland's, Inc; Standard Homeopathic Company
Street, Apt. No.; or PO Box No.: 210 West 131st Street
City, State, ZIP+4: Los Angeles, CA 90061-1618 (Nigh)

PS Form 3800, August 2006 See Reverse for Instructions

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name)

C. Date of Delivery 5/9/13

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7009 1680 0001 2306 3606

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

Law Offices of
Ronald A. Marron
A Professional Law Corporation
May 8, 2012

3636 Fourth Avenue, Ste 202
San Diego, CA 92103

Tel: 619.696.9006
Fax: 619.564.6665

Via: Certified Mail, (receipt acknowledgment with signature requested)

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

Jeffrey Margulies
Joseph H. Park
Stephanie Stroup
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071

RE: NOTICE: Violations of the California Consumer Legal Remedies Act and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this letter constitutes notice under the California Consumer Legal Remedies Act, ("CLRA"), California Civil Code Section 1750, *et seq.*, (the "ACT") — pursuant specifically to Civil Code Section 1782 — notifying **HYLAND's and STANDARD HOMEOPATHIC COMPANY** ("YOU" and "YOUR") of violations of the Act and of our demand that YOU remedy such violations within thirty (30) days from your receipt of this letter.

This firm represents Yuanke Xu, who purchased homeopathic products YOU distribute in California and elsewhere. For example, Mr. Xu purchased Hyland's Defend Cold & Cough, Cold n Cough 4 kids, and Hyland's Cough (Cold & Cough Products) at Henry's (now doing business as Sprouts), located in Oceanside, California. Mr. Xu was exposed to and saw YOUR claims about the products, purchased the product in reliance on those claims, and suffered injury in fact as a result of YOUR false and misleading advertising.

In purchasing Hyland's Cold & Cough products, Plaintiff relied upon various representations Defendants made on the product's label and elsewhere.

YOU falsely market YOUR homeopathic products by putting false and misleading claims on the labels. For example, YOU advertise Hyland's Defend Cold & Cough as "a comprehensive formula that offers relief for nasal congestion, cough, sore throat and sneezing symptoms". The claims on the label of Hyland's Cold & Cough products include statements such as: "Relief of: Congestion, Cough, Sore Throat, Sneezing,"

"Dye Free," "Alcohol Free," "Sugar Free, " among other representations. The claims on the label of Hyland's Cough include statements such as: "Natural Relief for Coughs Due to Colds".

In fact, all of YOUR homeopathic products, not only Hyland's Cold & Cough products, are essentially sugar pills with no efficacy beyond a placebo. Even if YOUR products contain the purportedly active ingredients, as listed on YOUR homeopathic products' labels, those ingredients are so greatly diluted as to be non-existent in the product, such that the product is ineffective for its intended uses. In addition, YOU omit the fact that the statements on YOUR products' labels have not been evaluated by the FDA.

A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding your products or services.

In conclusion, YOUR material misrepresentations are deceiving customers into purchasing YOUR products under the representation that they provide significant health benefits, when in fact they do not.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices in violation of the CLRA include, but are not necessarily limited to:

§ 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.

§ 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

§ 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

YOU have failed to honor your consumer protection obligations. Based upon the above, demand is hereby made that YOU conduct a corrective advertising campaign and destroy all misleading and deceptive advertising materials and products.

Please be advised that your failure to comply with this request within thirty (30) days may subject you to the following remedies, available for violations of the CLRA, which will be requested in the amended class action complaint on behalf of our client, Mr. Yuanke Xu, and all other similarly-situated California and U.S. residents:

(1) The actual damages suffered;

(2) An order enjoining you for such methods, acts or practices;

(3) Restitution of property (when applicable);

(4) Punitive damages;

(5) Any other relief which the court deems proper; and

(6) Court costs and attorneys' fees.

Additionally, I remind you of your legal duty to preserve all records relevant to such litigation. See, e.g., *Convolve, Inc. v. Compaq Computer Corp.*, 223 F.R.D 162, 175 (S.D.N.Y 2004); *Computer Ass'n Int'l v. American Fundware, Inc.*, 133 F.R.D. 166, 168-69 (D. Colo. 1990). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that related to the formulation and marketing of YOUR products will be sought in the forthcoming discovery process. You therefore must inform any employees, contractors, and third-party agents (for example product consultants and advertising agencies handling your product account) to preserve all such relevant information.

In addition, California Civil Code Section 1780 (b) provides in part that: "Any consumer who is a **senior citizen or a disabled person**, as defined in subdivision (f) and (g) of Section 1761, as part of an action under subdivision (a), may seek and be awarded, in addition to the remedied specified therein, up to **five thousand dollars** ($5,000)… [emphasis added]".

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

Sincerely,

THE LAW OFFICES OF RONALD A. MARRON APLC

/s/ Ronald A. Marron
Ronald A. Marron
Attorney for Yuanke Xu,
and all others similarly situated

U.S. Postal Service™
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Postage	$ 0.45	0161
Certified Fee	$2.75	15
Return Receipt Fee (Endorsement Required)	$2.55	Postmark Here
Restricted Delivery Fee (Endorsement Required)	$0.00	
Total Postage & Fees	$ $5.75	05/08/2012

7009 1680 0001 2306 3651

Sent To: Hyland's Inc; Standard Homeopathic Company
Street, Apt. No., or PO Box No.: 210 West 131st Street
City, State, ZIP+4: Los Angeles, CA 90061-1618 (XU)

PS Form 3800, August 2006 See Reverse for Instructions

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X HYLANDS ☐ Agent ☐ Addressee

B. Received by (Printed Name) C. Date of Delivery 5-9

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7009 1680 0001 2306 3651

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

Law Offices of
Ronald A. Marron
A Professional Law Corporation
May 8, 2012

3636 Fourth Avenue, Ste 202
San Diego, CA 92103

Tel: 619.696.9006
Fax: 619.564.6665

Via: Certified Mail, (receipt acknowledgment with signature requested)

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

Jeffrey Margulies
Joseph H. Park
Stephanie Stroup
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071

RE: NOTICE: Violations of the California Consumer Legal Remedies Act and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this letter constitutes notice under the California Consumer Legal Remedies Act, ("CLRA"), California Civil Code Section 1750, *et seq.*, (the "ACT") — pursuant specifically to Civil Code Section 1782 — notifying **HYLAND's and STANDARD HOMEOPATHIC COMPANY** ("YOU" and "YOUR") of violations of the Act and of our demand that YOU remedy such violations within thirty (30) days from your receipt of this letter.

This firm represents Diana Sisti, who frequently purchased homeopathic products YOU distribute in California and elsewhere. For example, Ms. Sisti purchased Hyland's Defend Cold & Cough Night at a CVS Pharmacy, located in San Diego, California. Ms. Sisti was exposed to and saw YOUR claims about the product, purchased the product in reliance on those claims, and suffered injury in fact as a result of YOUR false and misleading advertising.

In purchasing Hyland's Defend Cold & Cough Night, Plaintiff relied upon various representations Defendants made on the product's label and elsewhere, including: "Relief of: Sleeplessness, Congestion, Cough, Sore Throat, Sneezing," among other representations.

YOU falsely market YOUR homeopathic products by putting false and misleading claims on the labels. For example, YOU advertise Hyland's Defend Cold & Cough Night as "a comprehensive formula that offers relief for nasal congestion, cough, sore throat and sneezing symptoms plus calming support for sleeplessness, restless sleep or frequent

waking." The claims on the label of Hyland's Defend Cold & Cough Night include statements such as: "Safe and Effective Relief of: Sleeplessness, Congestion, Cough, Sore Throat, Sneezing," "Dye Free," "Alcohol Free," "Sugar Free, " among other representations. The purported active ingredients in this product include *Allium Cepa* 6X, *Coffea Cruda* 6X HPUS, *Chamomilla* 6X, *Hepar Sulph Calc* 12X HPUS, *Hydrastis* 6X HPUS, *Natrum Muriaticum* 6X HPUS, *Nux Vomica* 6X HPUS, *Phosphorus* 12X HPUS, *Pulsatilla* 6X HPUS and *Sulphur* 12X.

In fact, all of YOUR homeopathic products, not only Hyland's Defend Cold & Cough Night, are essentially sugar pills with no efficacy beyond a placebo. Even if YOUR products contain the purportedly active ingredients, as listed on YOUR homeopathic products' labels, those ingredients are so greatly diluted as to be non-existent in the product, such that the product is ineffective for its intended uses. In addition, YOU omit the fact that YOUR statements about YOUR products have not been evaluated by the FDA.

A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding your products or services.

In conclusion, YOUR material misrepresentations are deceiving customers into purchasing YOUR products under the representation that they provide significant health benefits, when in fact they do not.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices in violation of the CLRA include, but are not necessarily limited to:

§ 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.

§ 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

§ 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

YOU have failed to honor YOUR consumer protection obligations. Based upon the above, demand is hereby made that YOU conduct a corrective advertising campaign and destroy all misleading and deceptive advertising materials and products.

Please be advised that your failure to comply with this request within thirty (30) days may subject you to the following remedies, available for violations of the CLRA, which will be requested in the amended class action complaint on behalf of our client, Ms. Sisti, and all other similarly-situated California and U.S. residents:

(1) The actual damages suffered;

(2) An order enjoining you for such methods, acts or practices;

(3) Restitution of property (when applicable);

(4) Punitive damages;

(5) Any other relief which the court deems proper; and

(6) Court costs and attorneys' fees.

Additionally, I remind you of your legal duty to preserve all records relevant to such litigation. See, e.g., *Convolve, Inc. v. Compaq Computer Corp.*, 223 F.R.D 162, 175 (S.D.N.Y 2004); *Computer Ass'n Int'l v. American Fundware, Inc.*, 133 F.R.D. 166, 168-69 (D. Colo. 1990). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that related to the formulation and marketing of YOUR products will be sought in the forthcoming discovery process. YOU therefore must inform any employees, contractors, and third-party agents (for example product consultants and advertising agencies handling your product account) to preserve all such relevant information.

In addition, California Civil Code Section 1780 (b) provides in part that: "Any consumer who is a **senior citizen or a disabled person**, as defined in subdivision (f) and (g) of Section 1761, as part of an action under subdivision (a), may seek and be awarded, in addition to the remedied specified therein, up to **five thousand dollars** ($5,000)… [emphasis added]".

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

Sincerely,

THE LAW OFFICES OF RONALD A. MARRON APLC

/s/ Ronald A. Marron
Ronald A. Marron
Attorney for Ms. Sisti,
and all others similarly situated

U.S. Postal Service™
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Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$

Postmark Here

05/05/2011

7012 0470 0002 2191 8279

Sent To: Hyland's Inc; Standard Homeopathic Company
Street, Apt. No.; or PO Box No.: 210 West 131st Street
City, State, ZIP+4: Los Angeles, CA 90061 1618 (515th)

PS Form 3800, August 2006 — See Reverse for Instructions

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Hyland's Inc
Standard Homeopathic Company
210 West 131st Street
Los Angeles, CA 90061-1618

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) | C. Date of Delivery 5-9-11

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

☐ Yes

2. Arti
(Tra

PS Fo

2595-02-M-1540

Law Offices of
Ronald A. Marron
A Professional Law Corporation
May 15, 2012

3636 Fourth Avenue, Ste 202
San Diego, CA 92103

Tel: 619.696.9006
Fax: 619.564.6665

Via: Certified Mail, (receipt acknowledgment with signature requested)

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

Jeffrey Margulies
Joseph H. Park
Stephanie Stroup
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071

RE: NOTICE: Violations of the California Consumer Legal Remedies Act and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this letter constitutes notice under the California Consumer Legal Remedies Act, ("CLRA"), California Civil Code Section 1750, *et seq.*, (the "ACT") — pursuant specifically to Civil Code Section 1782 — notifying **HYLAND's and STANDARD HOMEOPATHIC COMPANY** ("YOU" and "YOUR") of violations of the Act and of our demand that YOU remedy such violations within thirty (30) days from your receipt of this letter.

This firm represents Yuanke Xu, who purchased homeopathic products YOU distribute in California and elsewhere. For example, Mr. Xu purchased Hyland's Seasonal Allergy Relief (Seasonal Allergy Relief) at Henry's (now doing business as Sprouts), located in Oceanside, California. Mr. Xu was exposed to and saw YOUR claims about the products, purchased the product in reliance on those claims, and suffered injury in fact as a result of YOUR false and misleading advertising.

In purchasing Seasonal Allergy Relief, Plaintiff relied upon various representations Defendants made on the product's label and elsewhere such that the product would relieve the symptoms of hay fever or other respiratory allergies from mold, animal dander, pollen, ragweed and grass.

YOU falsely market YOUR homeopathic products by putting false and misleading claims on the labels. For example, YOU advertise Seasonal Allergy Relief as "Non-Drowsy Formula" "For Indoor & Outdoor Allergies" that relieves "Itchy Watery Eyes,"

"Sneezing," "Runny Nose," and "Itchy Nose and Throat," is "100% Natural" and "Quick-Dissolving Tablets" among other representations.

In fact, all of YOUR homeopathic products, not only Seasonal Allergy Relief, are essentially sugar pills with no efficacy beyond a placebo. Even if Seasonal Allergy Relief contains the purportedly active ingredients, as listed on the product's label, those ingredients are so greatly diluted as to be non-existent in the product, such that the product is ineffective for its intended uses. In addition, YOU omit the fact that the statements on YOUR products' labels have not been evaluated by the FDA.

A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding your products or services.

In conclusion, YOUR material misrepresentations are deceiving customers into purchasing YOUR products under the representation that they provide significant health benefits, when in fact they do not.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices in violation of the CLRA include, but are not necessarily limited to:

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§ 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

§ 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

YOU have failed to honor your consumer protection obligations. Based upon the above, demand is hereby made that YOU conduct a corrective advertising campaign and destroy all misleading and deceptive advertising materials and products.

Please be advised that your failure to comply with this request within thirty (30) days may subject you to the following remedies, available for violations of the CLRA, which will be requested in the amended class action complaint on behalf of our client, Mr. Yuanke Xu, and all other similarly-situated California and U.S. residents:

(1) The actual damages suffered;

(2) An order enjoining you for such methods, acts or practices;

(3) Restitution of property (when applicable);

(4) Punitive damages;

(5) Any other relief which the court deems proper; and

(6) Court costs and attorneys' fees.

Additionally, I remind you of your legal duty to preserve all records relevant to such litigation. See, e.g., *Convolve, Inc. v. Compaq Computer Corp.*, 223 F.R.D 162, 175 (S.D.N.Y 2004); *Computer Ass'n Int'l v. American Fundware, Inc.*, 133 F.R.D. 166, 168-69 (D. Colo. 1990). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that related to the formulation and marketing of YOUR products will be sought in the forthcoming discovery process. You therefore must inform any employees, contractors, and third-party agents (for example product consultants and advertising agencies handling your product account) to preserve all such relevant information.

In addition, California Civil Code Section 1780 (b) provides in part that: "Any consumer who is a **senior citizen or a disabled person**, as defined in subdivision (f) and (g) of Section 1761, as part of an action under subdivision (a), may seek and be awarded, in addition to the remedied specified therein, up to **five thousand dollars** ($5,000)… [emphasis added]".

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

Sincerely,

THE LAW OFFICES OF RONALD A. MARRON APLC

/s/ Ronald A. Marron
Ronald A. Marron
Attorney for Yuanke Xu,
and all others similarly situated

Law Offices of
Ronald A. Marron
A Professional Law Corporation

3636 Fourth Avenue, Ste 202
San Diego, CA 92103

Tel: 619.696.9006
Fax: 619.564.6665

May 10, 2012

Via: Certified Mail, (receipt acknowledgment with signature requested

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

Jeffrey Margulies
Joseph H. Park
Stephanie Stroup
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071

RE: NOTICE: Violations of the California Consumer Legal Remedies Act and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this letter constitutes notice under the California Consumer Legal Remedies Act, ("CLRA"), California Civil Code Section 1750, *et seq.*, (the "ACT") — pursuant specifically to Civil Code Section 1782 — notifying **HYLAND's and STANDARD HOMEOPATHIC COMPANY** ("YOU" and "YOUR") of violations of the Act and of our demand that YOU remedy such violations within thirty (30) days from your receipt of this letter.

This firm represents Nancy Rodriguez, who frequently purchased homeopathic products YOU distribute in California and elsewhere. For example, Ms. Rodriguez purchased Hyland's Defense Cold & Cough Night at Whole Foods, located in Ormond Beach, Florida and Vitacost.com and Smartbomb.com online stores. Ms. Rodriguez was exposed to and saw YOUR claims about the product, purchased the product in reliance on those claims, and suffered injury in fact as a result of YOUR false and misleading advertising.

In purchasing Hyland's Defend Cold & Cough Night, Plaintiff relied upon various representations Defendants made on the product's label and elsewhere, including: "Safe and Effective Relief of: Sleeplessness, Congestion, Cough, Sore Throat, Sneezing," "Dye Free," "Alcohol Free," "Sugar Free, " among other representations.

YOU falsely market YOUR homeopathic products by putting false and misleading claims on the labels. For example, you advertise Hyland's Defend Cold & Cough Night as "a comprehensive formula that offers relief for nasal congestion, cough, sore throat and sneezing symptoms plus calming support for sleeplessness, restless sleep or frequent

waking." The claims on the label of Hyland's Defend Cold & Cough Night include statements such as: "Safe and Effective Relief of: Sleeplessness, Congestion, Cough, Sore Throat, Sneezing," "Dye Free," "Alcohol Free," "Sugar Free, " among other representations. The purported active ingredients in this product include *Allium Cepa* 6X HPUS, *Coffea Cruda* 6X HPUS, *Chamomilla* 6X HPUS, *Hepar Sulph Calc* 12X HPUS, *Hydrastis* 6X HPUS, *Natrum Muriaticum* 6X HPUS, *Nux Vomica* 6X HPUS, *Phosphorus* 12X HPUS, *Pulsatilla* 6X HPUS and *Sulphur* 12X HPUS.

In fact, all of YOUR homeopathic products, not only Hyland's Defend Cold & Cough Night, are essentially sugar pills with no efficacy beyond a placebo. Even if YOUR products contain the purportedly active ingredients, as listed on YOUR homeopathic products' labels, those ingredients are so greatly diluted as to be non-existent in the product, such that the product is ineffective for its intended uses. In addition, the statements omit the fact that the statements have not been evaluated by the FDA.

A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding your products or services.

In conclusion, YOUR material misrepresentations are deceiving customers into purchasing YOUR products under the representation that they provide significant health benefits, when in fact they do not.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices in violation of the CLRA include, but are not necessarily limited to:

§ 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.

§ 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

§ 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

YOU have failed to honor your consumer protection obligations. Based upon the above, demand is hereby made that YOU conduct a corrective advertising campaign and destroy all misleading and deceptive advertising materials and products.

Please be advised that your failure to comply with this request within thirty (30) days may subject you to the following remedies, available for violations of the CLRA, which will be requested in the first amended class action complaint on behalf of our client, Ms. Rodriquez, and all other similarly-situated California and U.S. residents:

(1) The actual damages suffered;

(2) An order enjoining you for such methods, acts or practices;

(3) Restitution of property (when applicable);

(4) Punitive damages;

(5) Any other relief which the court deems proper; and

(6) Court costs and attorneys' fees.

Additionally, I remind you of your legal duty to preserve all records relevant to such litigation. See, e.g., *Convolve, Inc. v. Compaq Computer Corp.*, 223 F.R.D 162, 175 (S.D.N.Y 2004); *Computer Ass'n Int'l v. American Fundware, Inc.*, 133 F.R.D. 166, 168-69 (D. Colo. 1990). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that related to the formulation and marketing of YOUR products will be sought in the forthcoming discovery process. You therefore must inform any employees, contractors, and third-party agents (for example product consultants and advertising agencies handling your product account) to preserve all such relevant information.

In addition, California Civil Code Section 1780 (b) provides in part that: "Any consumer who is a **senior citizen or a disabled person**, as defined in subdivision (f) and (g) of Section 1761, as part of an action under subdivision (a), may seek and be awarded, in addition to the remedied specified therein, up to **five thousand dollars** ($5,000)… [emphasis added]".

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

Sincerely,

THE LAW OFFICES OF RONALD A. MARRON APLC

/s/ Ronald A. Marron
Ronald A. Marron
Attorney for Ms. Rodriguez,
and all others similarly situated

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7012 0470 0002 2191 8152

Sent To: Hyland's Inc; Standard Homeopathic Company
Street, Apt. No.; or PO Box No.: 210 West 131st Street
City, State, ZIP+4: Los Angeles, CA 90061-1618 (Rodriguez)

PS Form 3800, August 2006 — See Reverse for Instructions

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Hyland's Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name): N. Hwisa
C. Date of Delivery: 5-11-12

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label): 7012 0470 0002 2191 8152

PS Form 3811, February 2004 — Domestic Return Receipt — 102595-02-M-1540

Law Offices of
Ronald A. Marron
A Professional Law Corporation

3636 Fourth Avenue, Ste 202
San Diego, CA 92103

Tel: 619.696.9006
Fax: 619.564.6665

June 4, 2012

Via: Certified Mail, (receipt acknowledgment with signature requested)

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

Jeffrey Margulies
Joseph H. Park
Stephanie Stroup
555 South Flower Street
Forty-First Floor
Los Angeles, California 90071

RE: NOTICE: Violations of the California Consumer Legal Remedies Act and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this letter constitutes notice under the California Consumer Legal Remedies Act, ("CLRA"), California Civil Code Section 1750, *et seq.*, (the "ACT") — pursuant specifically to Civil Code Section 1782 — notifying **HYLAND's and STANDARD HOMEOPATHIC COMPANY** ("YOU" and "YOUR") of violations of the Act and of our demand that YOU remedy such violations within thirty (30) days from your receipt of this letter.

This firm represents Diana Sisti, who purchased homeopathic products YOU distribute in California and elsewhere. For example, Ms. Sisti purchased Hyland's Defend Cold & Cough and Hyland's Migraine Headache Relief at a CVS Pharmacy, located in San Diego, California. Ms. Sisti was exposed to and saw YOUR claims about the products, purchased the products in reliance on those claims, and suffered injury in fact as a result of YOUR false and misleading advertising.

In purchasing Hyland's Defend Cold & Cough and Hyland's Migraine Headache Relief, Plaintiff relied upon various representations Defendants made on the products' labels and elsewhere, such as the products' names themselves and that the products would relieve Ms. Sisti's symptoms of migraine pain and common cold.

YOU falsely market YOUR homeopathic products by putting false and misleading claims on the labels. For example, YOU advertise Hyland's Defend Cold & Cough as "a comprehensive formula that offers relief for nasal congestion, cough, sore throat and sneezing symptoms". The claims on the label of Hyland's Cold & Cough include

statements such as: "Relief of: Congestion, Cough, Sore Throat, Sneezing," "Dye Free," "Alcohol Free," "Sugar Free, " among other representations. The purported active ingredients in this product include *Allium Cepa* (6X HPUS), *Hepar Sulph Calc* (12X HPUS), *Hydrastis* (6X HPUS), *Natrum Muriaticum* (6X HPUS), *Phosphorus* (12X HPUS), *Pulsatilla* (6X HPUS), *Sulphur* (12X HPUS).

Further, YOU advertise on the label of Hyland's Migraine Headache Relief that the product "temporarily relieves the symptoms of migraine pain," works fast to relieve migraine headache pain without aspirin, caffeine or sedatives," provides "100% Natural" "Migraine Headache Relief," and contains "Quick Dissolving tablets" that are "Aspirin free," among other representations. The purported active ingredients in this product include: *Glonoinum* 12X HPUS, *Belladonna* 6X HPUS, *Gelsemium* 6X HPUS, *Nux Vomica* 6X HPUS, *Iris Versicolor* 6X HPUS and *Sanguinaria Canadensis* 6X HPUS.

In fact, all of YOUR homeopathic products, not only Hyland's Defend Cold & Cough and Hyland's Migraine Headache Relief, are essentially sugar pills with no efficacy beyond a placebo. Even if YOUR products contain the purportedly active ingredients, as listed on YOUR homeopathic products' labels, those ingredients are so greatly diluted as to be non-existent in the products, such that the products are ineffective for their intended uses. In addition, YOU omit the fact that YOUR statements about YOUR products have not been evaluated by the FDA.

A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding your products or services.

In conclusion, YOUR material misrepresentations are deceiving customers into purchasing YOUR products under the representation that they provide significant health benefits, when in fact they do not.

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(2) An order enjoining you for such methods, acts or practices;

(3) Restitution of property (when applicable);

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///

///

June 4, 2012

Via: Certified Mail, (receipt acknowledgment with signature requested)

Hyland's, Inc.
Standard Homeopathic Company
Attn: Legal Department
210 West 131st Street
Los Angeles, CA 90061-1618

Jeffrey Margulies
Joseph H. Park
Stephanie Stroup
555 South Flower Street
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(4) Punitive damages;

(5) Any other relief which the court deems proper; and

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/ / /

/ / /

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

Sincerely,

THE LAW OFFICES OF RONALD A. MARRON APLC

Ronald A. Marron
Attorney for Ms. Sisti,
and all others similarly situated

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Sent To: Hyland's Inc; Standard Homeopathic Company.
Street, Apt. No.; or PO Box No.: 210 West 131st Street
City, State, ZIP+4: Los Angeles Ca 90061-1688

PS Form 3800, August 2006 — See Reverse for Instructions

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Hyland's Inc.
Standard Homeopathic Company
210 West 131st Street
Los Angeles, Ca 90061-1688

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) NAHJOSA C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7012 0470 0002 2191 9401

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540