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Counsel for Plaintiff and the Proposed Classes

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

LEO HARRIS, on behalf of himself, all others similarly situated and the general public,

Plaintiff,

v.

CVS PHARMACY, INC.,

Defendant.

Case No: EDCV13-2329 PSWL (AGRx)

CLASS ACTION

COMPLAINT FOR:

VIOLATIONS OF CALIFORNIA AND RHODE ISLAND CONSUMER PROTECTION STATUTES;

BREACHES OF EXPRESS AND IMPLIED WARRANTIES; AND

VIOLATIONS OF THE MAGNUSON-MOSS WARRANTY ACT

DEMAND FOR JURY TRIAL

LEO HARRIS, on behalf of himself, all others similarly situated, and the general public, by and through his undersigned counsel, hereby brings this action against Defendant CVS PHARMACY, INC. ("CVS") and alleges the following upon his own knowledge, or where he lacks personal knowledge, upon information and belief, including the investigation of his counsel.

INTRODUCTION

1. Coenzyme Q10, also known as CoQ10, is a compound that many companies sell in the form of a dietary supplement, and market and advertise as providing various benefits, especially to heart health. CoQ10 is often taken to help to treat or prevent congestive heart failure and has been used with anecdotal and varying success in treating or mitigating a variety of other conditions. The benefits of CoQ10 are well known to the consuming public, and especially consumers of dietary supplements.

2. While CoQ10 consumers generally understand the benefits of CoQ10, they also understand that the compound has one big drawback—it is very difficult for the human body to absorb CoQ10 through the digestive tract. Orally administered CoQ10 needs to be modified in some way to make it more absorbable. Consumers therefore look for technologies that increase the absorbability of CoQ10.

3. CoQ10 is a commodity product, with hundreds of different brands on the market. One of the primary ways brands distinguish themselves is with respect to absorbability.

4. CVS sells a CoQ10 product, branded as CVS/pharmacy Ultra CoQ-10 ("Ultra"), which makes repeated prominent claims on its packaging that the product has "6X BETTER ABSORPTION" and "over 600% better absorption" [1]:

[1] True and correct reproductions of CVS/pharmacy Ultra CoQ-10 packaging and label are attached hereto as Exhibit 1 and expressly incorporated into this Complaint.

5. These claims are false. Ultra does not rupture timely or at all, does not meet the industry-standard dissolution percentage for effectiveness, and therefore does not even come close to providing "6X" or "over 600%" "better absorption."

6. CVS attributes its "6X Better Absorption" claim to a 2009 study entitled *Relative Bioavailability Comparison of Different Coenzyme Q10 Formulations with a Novel Delivery System*.[2] Even disregarding the fact that Ultra does not timely rupture or sufficiently dissolve for adequate absorption, CVS's asserted *Relative Bioavailability* study does not support, but indeed demonstrates the falsity of CVS's blanket claims of "6X Better Absorption."

7. Plaintiff brings this class action to remedy the damage caused to consumers by CVS falsely advertising and selling its defective product.

[2] Z. Xia-Lui et al., *Relative Bioavailability Comparison of Different Coenzyme Q10 Formulations with a Novel Delivery System*, Alternative Therapies in Health & Medicine 15(2), at 42-46 (2009) [hereinafter "*Relative Bioavailability*"], attached hereto as Exhibit 2.

PARTIES

8. Plaintiff LEO HARRIS is a resident of Highland, California, in San Bernadino County.

9. Defendant CVS PHARMACY, INC. is a corporation organized and existing under the laws of the State of Rhode Island, with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895.

JURISDICTION & VENUE

10. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), the Class Action Fairness Act, because the matter in controversy exceeds the sum or value of $5,000,000 exclusive of interest and costs, and at least one member of the class of plaintiffs is a citizen of a State different from that of Defendant. In addition, more than two-thirds of the members of the class reside in states other than the state in which Defendant is a citizen and in which this case is filed, and therefore any exceptions to jurisdiction under 28 U.S.C. § 1332(d) do not apply. The Court also has jurisdiction pursuant to 28 U.S.C. § 1331 because this action contains claims arising under the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301 *et seq.* The Court has supplemental jurisdiction over the pendent state law claims pursuant to 28 U.S.C. § 1367, as they are so related to the claims within the Court's original jurisdiction that they form part of the same case or controversy.

11. The Court has personal jurisdiction over Defendant pursuant to Cal. Code Civ. P. § 410.10, as a result of Defendant's substantial, continuous, and systematic contacts with the State, and because Defendant has purposely availed itself of the benefits and privileges of conducting business activities within the State.

12. Venue is proper in this Central District of California pursuant to 28 U.S.C. § 1391(b) and (c), because Defendant resides (i.e., is subject to personal jurisdiction) in this district, and a substantial part of the events or omissions giving rise to the claims occurred in this district.

FACTS

I. COENZYME Q10

13. Coenzyme Q10 is a naturally occurring compound that is produced in various organs in the human body such as the heart, liver, kidneys and pancreas, and generates energy within human cells. It is commonly known in abbreviated form as CoQ10, and sometimes referred to as ubiquinone, ubidecarenone, or uniquinol, depending upon its form.

14. The amount of CoQ10 naturally produced in the body can be depleted by aging, heart disease and other chronic conditions, as well as by some medications, including statins used to lower cholesterol. Relatively small amounts of additional CoQ10 are available through certain foods, with the highest concentrations in meats and some vegetable oils. The most common method of increasing CoQ10 in the body is through dietary supplements.

15. CoQ10 has been proposed to treat a number of conditions, but such use is controversial. The United States Food and Drug Administration ("FDA") has not approved use of CoQ10 to treat any condition. As a result, CoQ10 is marketed widely as a dietary supplement, rather than a pharmaceutical. Companies that manufacture, advertise and sell CoQ10 dietary supplements make various health-related claims about the product, for example suggesting that CoQ10 supplements are good for the heart, and help treat or mitigate certain conditions, such as congestive heart failure.

16. CoQ10 is among the most popular dietary supplement in the U.S., with sales of over $500 million in 2011 alone.

II. USP STANDARDS FOR CoQ10 – RUPTURE AND DISSOLUTION

17. The U.S. Pharmacopeial Convention ("USP") is a nonprofit scientific organization whose participants, working under strict conflict-of-interest rules, set standards for dietary supplements that are enforceable by the FDA. These USP standards, known as Reference Standards, are published jointly by USP and the National Formulary in a compendia known as USP-NF. The Dietary Supplemental Health and Education Act of 1994 amendments to the Federal Food, Drug, and Cosmetic Act identify the USP-NF as the

"official compendium" for foods, including dietary supplements. 21 U.S.C. § 321(j); *see id.* § 343(s)(2)(D)-(E).

18. The USP-NF compendia consists of Monographs, General Chapters, and General Notices. Monographs include the name of an ingredient or preparation; its definition; its packaging, storage, and labeling requirements; and its specification, which consists of a series of tests, procedures for the tests, and acceptance criteria that require use of the official USP Reference Standards. General Chapters set forth tests and procedures referred to in multiple monographs. General Notices provide definitions for terms used in monographs, as well as information necessary to interpret monograph requirements.

19. A true and correct copy of the USP Monograph for CoQ10, under the formal designation Ubidecarenone Capsules, USP35 at 1461-62 ("USP CoQ10 Monograph"), is attached hereto as Exhibit 3, and expressly incorporated into this Complaint.

20. The USP CoQ10 Monograph (at page 1461) provides that ubidecarenone capsules, like the Ultra CoQ-10 soft gel capsules, "contain NLT [Not Less Than] 90.0% and NMT [Not More Than] 115.0% of the labeled amount of ubidecarenone."

21. In addition to setting the percentage of the actual amount of CoQ10 to the labeled amount, the USP has also determined the necessary percentage of dissolution for CoQ10. Dissolution of dietary supplements in the body is a necessary prerequisite to absorption because a capsule containing an active ingredient must dissolve in the body in order for the active ingredient to be released and absorbed into the bloodstream. The USP CoQ10 Monograph (at page 1462) provides that water-soluble forms of ubidecarenone, like the Ultra CoQ-10 soft gels, must "meet the requirements for the test for *Dissolution*," specifically requiring that "NLT [Not Less Than] 75% of the labeled amount of ubidecarenone . . . is dissolved."

22. In order for CoQ10 dietary supplements to dissolve, the capsules containing CoQ10 must timely rupture. This is a necessary prerequisite to adequate absorption because a pill that does not timely rupture will pass from the stomach to the intestines without

dissolution and then absorption commencing as quickly, if at all. The USP CoQ10 General Chapter on Disintegration and Dissolution of Dietary Supplements, USP-NF General Chapter <2040>, requires soft shell capsules like the Ultra CoQ-10 soft gels, to rupture "in not more than 15 minutes" (and "not more than 2 of the total of 18 capsules tested [must] rupture . . . [in] not more than 30 minutes"). A true and correct copy of USP-NF <2040> is attached hereto as Exhibit 4, and expressly incorporated into this Complaint.

23. In sum, as set forth by the well-defined USP industry standard, in order for water-soluble CoQ10 soft gel supplements like CVS's Ultra to be adequately absorbed into the bloodstream, they must first rupture within 15 minutes of ingestion, otherwise they pass through the rest of the human digestive system starting with the small intestines and thereby cannot sufficiently dissolve, even if the outer soft gel does eventually rupture sometime later. If the soft gel never ruptures, of course, both dissolution and absorption are impossible. In addition, even assuming timely rupture within 15 minutes, the level of dissolution for adequate absorption under USP guidelines must be 75%.

24. Dietary supplement manufacturers may voluntarily submit their products to USP for verification. USP performs laboratory analysis and determines whether the supplement is of sufficient quality, purity, and strength, and appropriately disintegrates and releases its contents into the body within a specified period of time. If the product meets the USP standards, the product may then bear a "USP Verified" seal.

III. CVS ULTRA CoQ-10

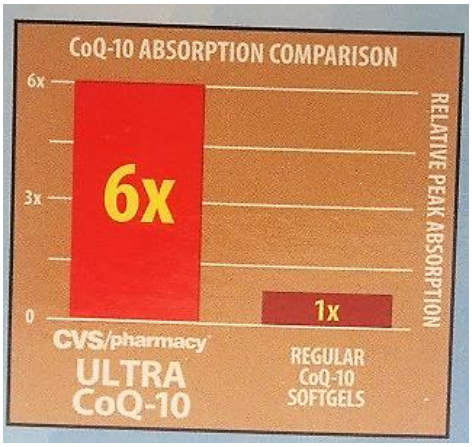
25. CVS sells Ultra CoQ-10 in its retail stores throughout the United States, including in California, for approximately $30.99 for a bottle containing 60 soft gel capsules.

26. Ultra is labeled to contain 100mg of CoQ10. Accordingly, pursuant to the CoQ10 Monograph, Ultra must contain at least 90mg of CoQ10, must rupture within 15 minutes of ingestion, and must exhibit at least 75% dissolution for adequate absorption.

27. CVS has not submitted Ultra for USP verification.

28. Ultra's packaging contains the following prominent representations a combined five times on each single box:

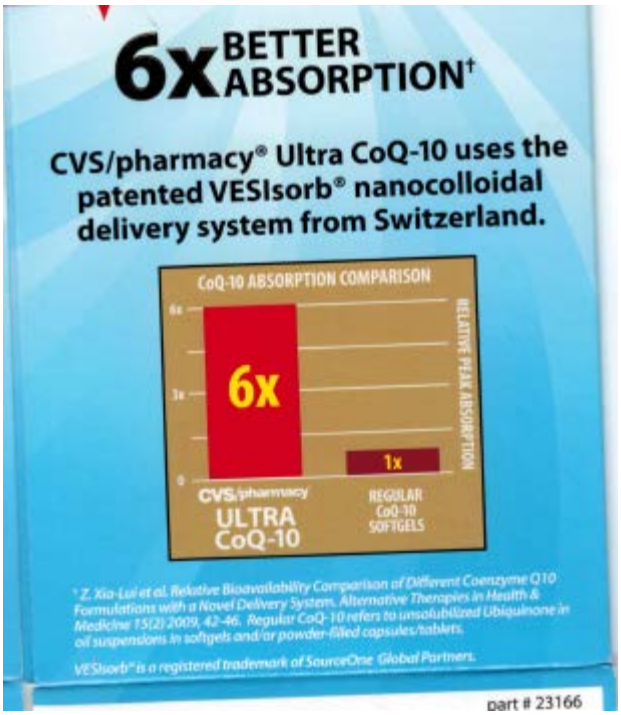
- "6X Better Absorption" (stated three times on the box)
- "CVS/pharmacy® Ultra CoQ-10 uses the patented VESIsorb® technology from Switzerland to achieve over 600% better absorption."
- A graphic "CoQ-10 ABSORPTION COMPARISON" chart, depicting the "6X" claim, comparing its claimed absorption to what the CVS packaging calls "Regular CoQ-10 Softgels," as follows:



29. Each of the "6X Better Absorption" claims refer to the following statement set forth at the bottom of the back panel in the smallest letters used on the box:

> † Z. Xia-Lui et al. Relative Bioavailability Comparison of Different Coenzyme Q10 Formulations with a Novel Delivery System. Alternative Therapies in Health & Medicine 15(2) 2009, 42-46. Regular CoQ-10 refers to unsolubilized Ubiquinone in oil suspensions in softgels and/or powder-filled capsules/tablets.

30. That statement appears on the box as replicated below, which is near 100% reproduction, e.g., actual life size:



31. Ultra's packaging also suggests that the product has certain health benefits, specifically by placing a claim on the package in three different places stating "HEART & MUSCLE HEALTH."

IV. PLAINTIFF'S PURCHASE OF CVS ULTRA CoQ-10

32. Plaintiff purchased CVS Ultra CoQ-10 in about the Summer of 2012 from the CVS store located at 7241 Boulder Avenue, in Highland, California. In purchasing Ultra, plaintiff relied on CVS's product claim as to "HEART & MUSCLE HEALTH," believing that the product would provide heart health benefits. Further, plaintiff decided to purchase Ultra rather than other CoQ10 dietary supplements specifically in reliance on CVS's repeated and prominent representations on the packaging that Ultra provides "6X" and "over 600%" "better absorption."

33. In fact, plaintiff decided to pay what he thought was a higher price for this product over the price of competitor CoQ10 dietary supplements specifically because of the comparative absorption representations on the Ultra box, which he understood to mean that

Ultra had 6X and over 600% better absorption than the competing CoQ10 products that he had also been purchasing.

V. CVS ULTRA CoQ-10 DIETARY SUUPLEMENTS DO NOT RUPTURE WITHIN 15 MINUTES, DO NOT HAVE 75% DISSOLUTION, AND DO NOT HAVE 6X OR 600% BETTER ABSORPTION

34. Independent laboratory testing, based on the USP test protocols, conclusively demonstrates that CVS Ultra CoQ-10 dietary supplements do not rupture within 15 minutes. On the contrary, out of 2 different bottles of CVS Ultra CoQ-10 dietary supplements, representing two different product lots, 7 out of 12 of the soft gel capsules tested did not rupture at all, even after 60 minutes; 3 out of the 12 experienced at best an immaterial, de minimis leakage of their contents, perhaps from a pinhole-size opening, but no discernable, visible rupture could be observed at all, even after 60 minutes; and only 2 soft gel capsules (1 from each of the two different lots) actually ruptured, but only after approximately 50 minutes.

35. In addition to establishing that 10 out of the 12 CVS Ultra CoQ-10 soft gel capsules from two different lots never even ruptured, the independent laboratory testing based on the USP test protocols also conclusively demonstrates that the 2 pills that did rupture (finally after 50 minutes) only had a dissolution rate of under 28% (specifically, 27.6% for one of the capsules, and 27.9% for the other).

36. True and correct copies of the reports of the above laboratory results are attached hereto as Exhibit 5, and expressly incorporated into this Complaint.

VI. CVS'S *RELATIVE BIOAVAILABILITY* STUDY DOES NOT SUPPORT BUT INSTEAD CONTRADICTS CVS'S "6X BETTER ABSORPTION" CLAIM

37. CVS's Ultra packaging cites to the *Relative Bioavailability* study, apparently as support for CVS's "6X Better Absorption" claims. This is false or misleading for a variety of reasons.

A. Flawed Study Design

i. Immaterial Sample Size

38. *Relative Bioavailability's* small sample size (just 20 subjects) allows for distortion by random chance, and magnifies bias. This is especially true because the human body is a complex environment. Thus, the results cannot possibly be considered reliable.

ii. Unrealistic Fasting Conditions

39. For the *Relative Bioavailability* study, CoQ10 dosing was made under fasting conditions. But most CoQ10 products instruct consumers to take with food. Even CVS's Ultra package itself sets forth, under "DIRECTIONS," a specific instruction to consumers to "take one (1) softgel daily with a meal":

40. The speed and rate of absorption of a dietary supplement is affected greatly by the nature and amount of food already existing in different parts of the human digestive system. Conducting a CoQ10 absorption comparison study under fasting conditions, as in the *Relative Bioavailability* study, dramatically skewers the results from what would be observed under real-life, non-fasting conditions.

41. This problem was reported in Ochiai A, Itagaki S, Kurokawa T, Kobayashi M, Hirano T, Iseki K, *Improvement in Intestinal Coenzyme Q10 Absorption by Food Intake*, Yakugaku Zasshi 127(8): 1251-1254 (2007), a true and correct copy of which is attached hereto as Exhibit 6.

iii. Improper Exclusion Criteria

42. The CVS Ultra package advertises that the product is "Beneficial for people taking cholesterol-lowering statin drugs." But the *Relative Bioavailability* study specifically excluded as test subjects those taking "Medication affecting cholesterol (eg, statins)."

43. CoQ10 is often taken by those with heart conditions seeking to improve and promote heart health, and the CVS Ultra package specifically advertises the product as "HEART & MUSCLE HEALTH." But the *Relative Bioavailability* study specifically excluded subjects with heart conditions.

44. CoQ10 supplements are most popular with the over-55 year old demographic. But the *Relative Bioavailability* study specifically excluded subjects over 60 years old (and does not even state the age of the subjects chosen).

45. In sum, the exclusion of test subjects with certain conditions and characteristics undermines the reliability of the *Relative Bioavailability* study in predicting the "real world" absorption results claimed by CVS on Ultra's label.

B. Failure to Reveal Comparators

46. The *Relative Bioavailability* study purports to demonstrate that the VESIsorb® technology offers superior absorption to other commercial CoQ10 formulations. But the study only compares VESIsorb® ("Product A") with undisclosed formulations, such as "Product B," "Product C," and "Product D," and only states that "Product A was provided by Vesifact AG, Baar, Switzerland," and "Products B, C, and D are commercially available CoQ10 products."

47. There are some CoQ10 formulations that, although they may technically be "commercially available," are nevertheless *not* adequate comparators for a variety of reasons.

By hiding the identity of the so-called "commercially available" comparators, the *Relative Bioavailablity* study is highly suspect and cannot be considered reliable support for CVS's grandiose claims of "6X Better Absorption."

C. Limited Initial Results With No "Verification" of "Clinical Response"

48. The *Relative Bioavailability* study concludes that because "there is substantial variation in people's ability to absorb CoQ_{10} in the normal population[, a]dditional clinical studies are indicated to verify that the improved absorption with [VESIsorb®] correlated with clinical response to treatment." *Relative Bioavailability* at 46 (internal citations omitted).

49. Thus, by its own admission, the *Relative Bioavailability* study does not actually "verify" anything, and certainly not any "clinical response" "correlated" to the alleged "improved absorption with [the asserted patented VESIsorb® technology]," especially when extrapolated to the general population.

D. Bias & Sponsorship

50. As noted above, CVS claims its increased absorption comes from a patented technology, specifically stating on its Ultra box that "CVS/pharmacy® Ultra CoQ-10 uses the patented VESIsorb® technology from Switzerland to achieve over 600% better absorption." Also as noted above, the "Product A" formulation using the VESIsorb® technology that was tested in the *Relative Bioavailability* study was provided by Vesifact AG, Baar, Switzerland.

51. The *Relative Bioavailability* study thus cannot be considered independent. For example, as stated in the study, "[t]he work [of the study] was funded by Vesifact AG, Baar, Switzerland." And one of the two authors of the study, Carl Artmann, "served as paid consultant[ ] to Vesifact in monitoring and analyzing this study . . . ."

52. In addition, an Illinois company called SourceOne Global Partners, LLC owns one or more patents covering the VESIsorb® technology. The other author of the *Relative Bioavailability* study, Zheng-Xian Liu, "served as a paid consultant to SourceOne Global Partners in the preparation of th[e] manuscript [of the study] . . . ."

53. Despite stating that both authors of the study hold "no other financial interest in the products of technologies studied or in either Vesifact or SourceOne," the fact that the study was funded by and conducted on behalf of companies that indeed have a significant financial interest in its outcome undermines the credibility and reliability of the study.

E. On Its Face, The *Relative Bioavailability* Actually Contradicts CVS's Labeling Claims for Ultra

54. Even if the *Relative Bioavailability* study were reliable, it does not support CVS's labeling claims of "6X" and "over 600%" "Better Absorption," but instead contradicts them.

55. In particular, the *Relative Bioavailability* study concludes that "the relative bioavailability of product A" - the CoQ10 supplement allegedly employing the VESIsorb® technology as used in CVS Ultra - was just "**499%** [compared] to product B, and **286%** to product D."

56. Although the *Relative Bioavailability* study concludes that VESIsorb® provides 622% bioavailability compared to "Product C," CVS deceptively omits on Ultra's label that the product purportedly offers "6X" or "over 600%" "Better Absorption" on only one of three other types of CoQ-10 supplements tested. Instead, the CVS Ultra package purports to compare Ultra's absorption simply to what it calls "REGULAR CoQ-10 SOFTGELS" - deceptively employing the plural. And as noted above, nowhere does the study (or the CVS Ultra package) identify the actual one supplement upon which CVS Ultra bases its "6x" and "over 600%" comparative absorption claim, raising suspicion as to the extent to which that other supplement is an appropriate comparator.

CVS'S UNLAWFUL ACTS & PRACTICES

I. CVS SELLS DEFECTIVE ULTRA CoQ-10 DIETARY SUPPLEMENTS

57. As noted above, CVS's Ultra softgels do not rupture within 15 minutes or even 30 minutes, or in most cases even after 60 minutes. Consequently, they provide consumers with little or no benefit, and are ineffective and indeed defective.

58. Even if Ultra did timely rupture, it fails to adequately dissolve – at best exhibiting a dissolution rate of under 28%, far below the USP standard of 75%, thereby further providing little or no benefit to consumers, also rendering the product ineffective and indeed defective.

II. CVS EMPLOYS FALSE AND DECEPTIVE ULTRA PRODUCT CLAIMS

A. CVS's Affirmative Misrepresentations

59. Because CVS Ultra does not rupture timely or at all, and exhibits at best under 28% dissolution, the product cannot possibly provide adequate absorption for any reasonable effectiveness, and cannot possibly provide "6X" and "over 600%" "Better Absorption" over other widely available brands of CoQ10 dietary supplements, especially on any consistent basis as compared to materially competitive products. Accordingly, CVS's claim that Ultra provides "6X" and "over 600%" "Better Absorption" is literally false.

60. In addition, CVS's use of the ambiguous phrase "Regular CoQ-10 Softgels" in referring to the one type of supplement (Product A) out of the three that are the subject of the *Relative Bioavailability* study as a basis for its absorption comparison claims, is an intentionally confusing and deceptive representation. And by comparing Ultra to these so-called "Regular CoQ-10 Softgels," CVS's representations that Ultra provides "6X" and "over 600%" "Better Absorption" are at a minimum materially misleading and deceptive.

61. CVS's reference to the *Relative Bioavailability* study on its Ultra package as apparent support for its comparative absorption claims is also literally false or at least materially misleading and deceptive, since that study expressly demonstrates that the CoQ10 supplement employing the same VESIsorb technology as Ultra (Product A) provided far less

than 600% better absorption than two of the three other products tested, specifically only 499% and 286%.

62. CVS's reference to the *Relative Bioavailability* study is also materially misleading and deceptive because the study is so poorly designed (small sample size, unrealistic fasting conditions, improper exclusion criteria), fails to identify any of the comparators, and actually admits that it cannot be used to "verify" anything – rendering the study's results completely unreliable.

63. CVS's repeated reference on its Ultra package suggesting that the product benefits "HEART & MUSCLE HEALTH" is also literally false or at least materially misleading and deceptive, since the product is defective by not adequately rupturing and dissolving, and therefore provides no or little possible benefit to heart and muscle health.

B. CVS's Omissions of Material Fact

64. In labeling Ultra, CVS deceptively omitted information that would have been material to consumers' purchasing decisions.

65. For example, CVS fails to disclose that its Ultra softgels do not adequately rupture and dissolve, both of which render CVS's comparative absorption claims implausible, indeed impossible.

66. CVS also fails to disclose that its cited *Relative Bioavailability* study (i) was funded and performed by or on behalf of companies with a financial interest in the outcome of the study, (ii) is based on an improper design employing an immaterial sample size, unrealistic fasting conditions (despite the product's instruction to take the supplement "with a meal"), and improperly excludes subjects with heart conditions and those over 60 years old, (iii) does not disclose the identity of the comparators, and (iii) contains an express admission that the study cannot actually "verify" anything.

67. CVS also fails to disclose that its cited *Relative Bioavailability* study shows that the formulation used for Ultra provides far less than 600% better absorption for two of the

three other formulations tested, specifically only 499% and 286% more absorption than those two other products.

PLAINTIFF'S RELIANCE AND INJURY

68. For his purchase of Ultra, plaintiff relied on CVS's repeated, prominent representation that the product provides "6X" or "over 600%" "Better Absorption" than competing, so-called "Regular" CoQ10 dietary supplements. In addition, plaintiff relied on CVS's representations that Ultra generally supports heart and muscle health.

69. But Ultra does not provide six times better absorption than fair marketplace comparators. Because Ultra is actually ineffective, plaintiff did not receive what he paid for, and lost money in the full amount of his Ultra purchases.

70. Plaintiff purchased Ultra instead of competing products based on the false statements and misrepresentations described herein.

71. Ultra was unsatisfactory to plaintiff because it did not provide the full benefit advertised, and may have provided no benefit.

72. Plaintiff would not have purchased Ultra absent CVS's false and misleading representation about its "6X" and "over 600%" better absorption. He would not have paid the price he did for Ultra, which is sold at a significant premium to some competing products, if he knew that Ultra does not rupture at all or timely, does not dissolve at all or to any substantial degree (and certainly far less dissolution than industry standard as reflected in the USP CoQ10 Monograph), and does not provide "6X" and "over 600%" better absorption than other brands of which he was aware and may have otherwise purchased.

CLASS ACTION ALLEGATIONS

73. Pursuant to Rule 23, Fed. R. Civ. P., plaintiff seeks to represent a Nationwide Class comprised of all persons in the United States who purchased CVS Ultra primarily for personal, family, or household use, and not for resale.

74. Pursuant to Rule 23, plaintiff also seeks to represent a California Subclass comprised of all persons in California who purchased CVS Ultra primarily for personal, family, or household use, and not for resale.

75. The members in the proposed class and subclass are so numerous that individual joinder of all members is impracticable, and the disposition of the claims of all class members in a single action will provide substantial benefits to the parties and Court. Questions of law and fact common to plaintiff and the class and subclass include:

(i.) Whether Ultra fails to timely rupture;

(ii.) Whether Ultra fails to provide adequate dissolution;

(iii.) Whether CVS's "6X" and "over 600%" "better absorption" claims are false or misleading, or likely to deceive the public, in light of Ultra's failure to timely rupture or adequately dissolve;

(iv.) Whether CVS's "6X" and "over 600%" "better absorption" claims are material to reasonable consumers;

(v.) Whether CVS's "HEART & MUSCLE HEALTH" claims are false or misleading, or likely to deceive the public, in light of Ultra's failure to timely rupture or adequately dissolve;

(vi.) Whether CVS's "HEART & MUSCLE HEALTH" claims are material to reasonable consumers;

(vii.) Whether CVS's claim that Ultra is "beneficial for people faking cholesterol-lowering statin drugs" is false or misleading, or likely to deceive the public, in light of Ultra's failure to timely rupture or adequately dissolve;

(viii.) Whether CVS's claim that Ultra is "beneficial for people faking cholesterol-lowering statin drugs" is material to reasonable consumers;

(ix.) Whether CVS made any statement it knew or should have known was false or misleading;

(x.) Whether any of CVS's practices were immoral, unethical, unscrupulous, or substantially injurious to consumers;

(xi.) Whether the utility of any of CVS's practices outweighed the gravity of the harm to its victims;

(xii.) Whether CVS's conduct affronts public policy, as delineated by the common law, statutes, and other established concepts of unfairness, or violated public policy as declared by specific constitutional, statutory or regulatory provisions;

(xiii.) Whether the consumer injury caused by CVS's conduct was substantial, not outweighed by benefits to consumers or competition, and not one that consumers themselves could reasonably have avoided;

(xiv.) Whether CVS's conduct or any of its acts or practices violated the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2103 *et seq.*, the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, the Rhode Island Unfair Trade Practices & Consumer Protection Act, §§ R.I. Gen. L. § 6-13.1-1, *et seq.*, the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.*, the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*, or any other law;

(xv.) Whether CVS represented that Ultra has characteristics, uses, or benefits which it does not have, within the meaning of Cal. Civ. Code § 1770(a)(5);

(xvi.) Whether CVS represented Ultra is of a particular standard, quality, or grade, when it was really of another, within the meaning of Cal. Civ. Code § 1770(a)(7);

(xvii.) Whether CVS disparaged the goods, services, or business of another by false or misleading representation of fact, within the meaning of Cal. Civ. Code § 1770(a)(8);

(xviii.) Whether CVS advertised Ultra with the intent not to sell it as advertised, within the meaning of Cal. Civ. Code § 1770(a)(9);

(xix.) Whether CVS represented that Ultra has been supplied in accordance with a previous representation when it has not, within the meaning of Cal. Civ. Code § 1770(a)(16);

(xx.) Whether through Ultra's labeling claims, CVS made express or implied warranties to purchasers;

(xxi.) Whether CVS breached express warranties by failing to provide Ultra in conformance with promises or descriptions that became a basis for the bargain;

(xxii.) Whether CVS breached implied warranties by failing to provide merchantable goods in selling Ultra to the class members, or by selling Ultra that was not fit for its particular purpose of supplementing the body's natural CoQ10 production;

(xxiii.) Whether CVS is a "merchant" and Ultra a "good" within the meaning of R.I. Gen. L. §§ 6A-2-104 & 6A-2-105(1);

(xxiv.) Whether CVS's representation that Ultra provides "6X Better Absorption" was an affirmation of fact or promise that CVS made to plaintiff and the class members, which became part of the basis of the bargain, or was a description of the goods that was made part of the bargain.

(xxv.) Whether Ultra has actually malfunctioned or a defect manifested itself and whether, as a result, CVS breached its implied warranties of merchantability and fitness pursuant to R.I. Gen. L. §§ 6A-2-314(2)-(3) and 6A-2-315;

(xxvi.) Whether Ultra is a consumer product, whether the class members are consumers, and whether CVS is a supplier and warrantor, within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301;

(xxvii.) Whether CVS's policies, acts, and practices with respect to Ultra were designed to, and did result in the purchase and use of Ultra by the class members primarily for personal, family, or household purposes;

(xxviii.) The proper equitable and injunctive relief;

(xxix.) The proper amount of actual or compensatory damages;

(xxx.) The proper amount of restitution or disgorgement;

(xxxi.) The proper amount of punitive damages; and

(xxxii.) The proper amount of reasonable litigation expenses and attorneys' fees.

76. Plaintiff's claims are typical of class members' claims in that they are based on the same underlying facts, events, and circumstances relating to CVS's conduct.

77. Plaintiff will fairly and adequately represent and protect the interests of the classes, has no interests incompatible with the interests of the classes, and has retained counsel competent and experienced in class litigation.

78. The Nationwide Class and the California Subclass each are sufficiently large for purposes of class litigation since each contains at least thousands of members who purchased the CVS Ultra at issue in this action.

79. Class treatment is superior to other options for resolution of the controversy because the relief sought for each class member is relatively small such that, absent representative litigation, it would be infeasible for class members to redress the wrongs done to them.

80. Questions of law and fact common to the classes predominate over any questions affecting only individual class members.

81. As a result of the foregoing, class treatment is appropriate under Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3).

FIRST CAUSE OF ACTION

VIOLATIONS OF THE CALIFORNIA UNFAIR COMPETITION LAW, CAL. BUS. & PROF. CODE §§ 17200 *ET SEQ.*

(By the California Class)

82. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

83. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice," Cal. Bus. & Prof. Code § 17200.

Fraudulent

84. CVS's claim that Ultra provides "6X Better Absorption," generally supports heart and muscle health, and is beneficial to statin users, is false or misleading, and fraudulent under the UCL, because Ultra is actually ineffective. Ultra's label is likely to deceive a reasonable consumer and the public.

85. CVS's omissions of material facts as set forth herein are also prohibited by the UCL's "fraudulent" prong.

Unfair

86. CVS's conduct with respect to the labeling, advertising, and sale of Ultra was unfair because its conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

87. CVS's conduct with respect to the labeling, advertising, and sale of Ultra was also unfair because it violated public policy as declared by specific constitutional, statutory or regulatory provisions, including but not limited to the False Advertising Law, portions of the Federal Food, Drug, and Cosmetic Act, portions of the Dietary Supplement Health and Education Act of 1994, and portions of the California Sherman Food, Drug, and Cosmetic Law.

88. CVS's conduct with respect to the labeling, advertising, and sale of Ultra was also unfair because the consumer injury was substantial, not outweighed by benefits to consumers or competition, and not one consumers themselves could reasonably have avoided.

Unlawful

89. The acts alleged herein are "unlawful" under the UCL in that they violate at least the following laws:

- The Magnuson-Moss Warrant Act, 15 U.S.C. §§ 2103 *et seq.*;
- The Lanham Act, 15 U.S.C. §§ 1501 *et seq.*;
- The Rhode Island Unfair Trade Practice and Consumer Protection Act, R.I. Gen. L. §§ 6-13.1-1, *et seq.*;
- The False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.*; and
- The Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*

* * *

90. In accordance with Cal. Bus. & Prof. Code § 17203, plaintiff seeks an Order enjoining CVS from continuing to conduct business through unlawful, unfair, or fraudulent acts and practices, and to commence a corrective advertising campaign.

91. On behalf of himself and the classes, plaintiff also seeks an Order for the restitution of all monies from the sale of Ultra, which were unjustly acquired through acts of unlawful, unfair, or fraudulent competition.

SECOND CAUSE OF ACTION

VIOLATIONS OF THE CALIFORNIA FALSE ADVERTISING LAW, CAL. BUS. & PROF. CODE §§ 17500 *ET SEQ.*

(By the California Class)

92. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

93. The FAL prohibits any statement in connection with the sale of goods "which is untrue or misleading," Cal. Bus. & Prof. Code § 17500.

94. CVS's claims that Ultra provides "6X Better Absorption," and generally supports heart and muscle health, are untrue or misleading in that CVS CoQ10 is ineffective.

95. CVS knew, or reasonably should have known, that the claims were untrue or misleading.

96. Plaintiff and the California Class are entitled to injunctive and equitable relief, and restitution in the amount they spent on the CVS Ultra.

THIRD CAUSE OF ACTION

VIOLATIONS OF THE CALIFORNIA CONSUMERS LEGAL REMEDIES ACT, CAL. CIV. CODE §§ 1750 *ET SEQ.*

(By the California Class)

97. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

98. The CLRA prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.

99. CVS's policies, acts, and practices were designed to, and did, result in the purchase and use of the products primarily for personal, family, or household purposes, and violated and continue to violate the following sections of the CLRA:

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

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

c. CVS disparaged the goods, services, or business of another by false or misleading representation of fact, within the meaning of Cal. Civ. Code §

1770(a)(8);

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

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

100. As a result, plaintiff and the class members have suffered irreparable harm and are entitled to injunctive relief, their actual damages, punitive damages, and reasonable attorneys' fees and costs.

101. In compliance with Cal. Civ. Code § 1782, on October 31, 2013, plaintiff sent written notice to CVS of his claims. CVS's agent for service of process in California received notice on November 4, 2013, and CVS also received notice at its headquarters on November 11, 2013.

102. In compliance with Cal. Civ. Code § 1782(d), plaintiff's affidavit of venue is filed concurrently herewith, attached to the Complaint as Exhibit 7.

FOURTH CAUSE OF ACTION

VIOLATION OF THE RHODE ISLAND UNFAIR TRADE PRACTICE AND CONSUMER PROTECTION ACT, R.I. GEN. L. §§ 6-13.1-1 *ET SEQ.*

(By the Nationwide Class)

103. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

104. The Rhode Island Consumer Protection Act provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." R.I. Gen. L. § 6-13.1-2.

105. CVS's claims that Ultra provides "6X Better Absorption," and generally supports heart and muscle health, are false and misleading because Ultra is actually ineffective.

106. This advertising is a deceptive act or practice committed while engaged in a business of trade or commerce, within the meaning of the statute. *See* R.I. Gen. L. § 6-13.1-1(6)(i)-(iii), (v), (vii)-(ix), (xii)-(xiv), (xvi)-(xvii).

107. Moreover, CVS's practices affront public policy, as delineated by the common law, statutes, and other established concepts of unfairness; are immoral, unethical, oppressive, or unscrupulous; and cause substantial injury to consumers.

108. Pursuant to R.I. Gen. L. §§ 6-13.1-5.2(a)-(b) & (d), plaintiff and the Nationwide Class are entitled to their actual damages, or $200 per violation, whichever is greater; attorneys' fees and costs; injunctive or other equitable relief; and—if CVS's conduct was willful, reckless, or wicked—punitive damages.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY, CAL. COMM. CODE § 2313

(By the California Class)

109. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

110. There was a sale of goods from CVS to plaintiff and the class members.

111. CVS made an affirmation of fact or promise that Ultra provides "6X better absorption" than competing products. This affirmation of fact, promise or description formed part of the basis of the bargain. CVS thus expressly warranted the goods sold.

112. CVS breached the warranty in that Ultra was ineffective.

113. Plaintiff and the class members suffered injury as a result of CVS's breach in that they paid money for an ineffective product.

114. Prior to filing this suit, plaintiff, on behalf of himself and the class, gave CVS notice of the breach.

115. Plaintiff, on behalf of himself and the class, seeks actual damages for CVS's breach of warranty.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY, CAL. COMM. CODE § 2313(1)

(By the California Class)

116. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

117. "Unless excluded or modified . . . a warranty that goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Cal. Comm. Code § 2314(1).

118. There was a sale of goods from CVS to plaintiff and the class members.

119. CVS impliedly warranted the goods sold were merchantable.

120. CVS breached the warranty in that Ultra was ineffective.

121. Plaintiff and the class members suffered injury as a result of CVS's breach in that they paid money for an ineffective product.

122. Prior to filing this action, plaintiff, on behalf of himself and the class, gave CVS notice of the breach.

123. Plaintiff, on behalf of himself and the class, seeks actual damages for CVS's breach of warranty.

SEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF FITNESS, CAL. COMM. CODE § 2315

(By the California Class)

124. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

125. "Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or

judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." Cal. Comm. Code § 2315.

126. There was a sale of goods from CVS to plaintiff and the class members.

127. CVS impliedly warranted the goods sold were fit for their particular purpose, *i.e.*, supplementing the body's natural Coenzyme Q10 production.

128. CVS breached the warranty in that Ultra was ineffective.

129. Plaintiff and the class members suffered injury as a result of CVS's breach in that they paid money for an ineffective product.

130. Prior to filing this sui, plaintiff, on behalf of himself and the class, gave CVS notice of the breach.

131. Plaintiff, on behalf of himself and the class, seeks actual damages for CVS's breach of warranty.

EIGHTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY, R.I. GEN. L. § 6A-2-313

(By the Nationwide Class)

132. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

133. CVS is "merchant," and Ultra a "good" within the meaning of R.I. Gen. L. §§ 6A-2-104 & 6A-2-105(1).

134. CVS's representation that Ultra provides "6X Better Absorption" is an affirmation of fact or promise CVS made to plaintiff and the class members that became part of the basis of the bargain.

135. CVS's representation that Ultra provides "6X Better Absorption" is also a description of the goods which was made part of the bargain.

136. Accordingly, CVS's representation was an express warranty, that Ultra shall conform to the promise and description. R.I. Gen. L. §§ 6A-2-313(1)(a)-(b).

137. Plaintiff and the class members were damaged by CVS's breach of the express warranty. Because Ultra was actually ineffective, plaintiff and the class members lost money in the amount of their purchases.

138. Prior to filing this suit, plaintiff, on behalf of himself and the class, gave CVS notice of the breach.

139. Plaintiff, on behalf of himself and the class, seeks actual damages for CVS's breach of warranty.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY, R.I. GEN. L. § 6a-2-314

(By the Nationwide Class)

140. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

141. CVS is a merchant with respect to goods of Ultra's kind, e.g., dietary supplements, and more specifically, CoQ10 supplements.

142. In selling Ultra to plaintiff and the class members, CVS impliedly warranted that the goods sold were merchantable, but Ultra fails to adequately rupture or dissolve.

143. Specifically, CVS breached its implied warranty of merchantability in at least the following ways, *see* R.I. Gen. L. § 6A-2-314(3):

(a) Ultra would not "[p]ass without objection in the trade under the contract description," R.I. Gen. L. § 6A-2-314(2)(a);

(b) Ultra is not "of fair average quality within the description," R.I. Gen. L. § 6A-2-314(2)(b);

(c) Ultra is not "fit for the ordinary purposes for which such goods are used," R.I. Gen. L. § 6A-2-314(2)(c);

(d) Ultra does not "[r]un, within the variations permitted by the agreement, of even kind, quality, and quantity within each unit and among all units involved," R.I. Gen. L. § 6A-2-314(2)(d);

(e) Ultra is not "adequately contained, packaged, and labeled as the agreement may require," R.I. Gen. L. § 6A-2-314(2)(e); and

(f) Ultra does not "[c]onform to the promises or affirmations of fact made on the container or label if any," R.I. Gen. L. § 6A-2-314(2)(f).

144. Plaintiff and the class members suffered injury as a result of CVS's breach in that they paid money for a product that does not adequately rupture or dissolve, or provide the benefits advertised.

145. Prior to filing this suit, plaintiff, on behalf of himself and the class, gave CVS notice of the breach.

146. Plaintiff, on behalf of himself and the class, seeks actual damages for CVS's breach of warranty.

TENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF FITNESS, R.I. GEN. L. § 6A-2-315

(By the Nationwide Class)

147. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

148. In selling Ultra to plaintiff and the class members, CVS had reason to know the particular purpose for which the goods were required, e.g., supplementing the body's CoQ10 production.

149. In selling Ultra to plaintiff and the class members, CVS had reason to know that buyers were relying on CVS's skill or judgment to furnish suitable goods.

150. Accordingly, there was an implied warranty that the Ultra was fit for its purpose. R.I. Gen. L. § 6A-2-315.

151. CVS breached the warranty in that Ultra, because it was ineffective, was not fit to supplement the CoQ10 production of plaintiff's and the class members' bodies.

152. Plaintiff and the class members suffered injury as a result of CVS's breach in that they paid money for an product that did not work and was not fit for its purpose.

153. Prior to filing this suit, plaintiff, on behalf of himself and the class, gave CVS notice of the breach.

154. Plaintiff, on behalf of himself and the class, seeks actual damages for CVS's breach of warranty.

ELEVENTH CAUSE OF ACTION

VIOLATIONS OF THE MAGNUSON-MOSS WARRANTY ACT, 15 U.S.C. §§ 2301 *ET SEQ.*

(By the Nationwide Class)

155. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

156. Ultra is a consumer product within the meaning of 15 U.S.C. § 2301(1).

157. Plaintiff and the class members are consumers within the meaning of 15 U.S.C. § 2301(3).

158. Defendant CVS is a supplier and warrantor as defined in 15 U.S.C. §§ 2301(4) & (5).

159. The Magnuson-Moss Warranty Act permits a consumer to recover damages caused "by the failure of a supplier, warrantor, or service contractor to comply with any obligation under his [Act], or under a written warranty, implied warranty, or service contract." 15 U.S.C. § 2310(d)(1).

160. CVS's claim that Ultra provides "6X Better Absorption" or "over 600% better absorption" is a "written warranty" within the meaning of the Act because it is an "affirmation of fact or written promise made in connection with the sale of" the product, "which relates to

the nature of the material . . . and affirms or promises that such material . . . is defect free or will meet a specified level of performance . . . .” 15 U.S.C. § 2301(6)(A).

161. As set forth herein, Ultra does not provide “6X Better Absorption” as warranted.

162. The CVS Ultra’s “Money Back Guarantee” is also a “written warranty” within the meaning of the Act because it is an “undertaking in writing in connection with the sale” of the product “to refund . . . or take other remedial action with respect to such product in the event that such product fails to meet the specifications set forth in the undertaking,” *id.* § 2301(b)(B).

163. Although Ultra does not meet the “6X” specification, CVS has so far failed to refund its purchasers their money, even after plaintiff, on behalf of the class, made a pre-litigation demand for such relief on behalf of himself and the class.

164. By reason of CVS’s breach of these express written warranties, CVS has violated the statutory rights due plaintiff and the class members pursuant to the Magnuson-Moss Warranty Act, thereby damaging plaintiff and the class members. 15 U.S.C. §§ 2301 *et seq.*

165. Plaintiff and the class were injured as a direct and proximate result of CVS’s breach because: (a) they would not have purchased Ultra on the same terms if the true facts concerning its purported “better absorption” had been known to them; (b) they paid a price premium due to CVS’s misleading representations that Ultra provides “6X Better Absorption,” and (c) Ultra does not perform as promised (or at all).

166. Plaintiff, on behalf of himself and the class members, seeks damages, equitable relief, and attorney’s fees and costs pursuant to 15 U.S.C. §§2310(d)(1),(2).

PRAYER FOR RELIEF

167. Wherefore, Plaintiff, on behalf of himself, all others similarly situated and the general public, prays for judgment against CVS as to each and every cause of action, including:

A. An Order certifying this as a class action and appointing plaintiff and his counsel to represent the classes;

B. An Order enjoining CVS from selling Ultra so long as the product fails to timely rupture or provide adequate dissolution;

C. An Order enjoining CVS from labeling, advertising, or packaging Ultra with any claim of "better absorption," "heart & muscle health," or "beneficial to people taking cholesterol-lowering statin drugs";

D. An Order compelling CVS to conduct a corrective advertising campaign to inform the public that Ultra was ineffective;

E. An Order requiring CVS to disgorge or return all monies, revenues, and profits obtained by means of any wrongful act or practice;

F. An Order requiring CVS to pay all actual and statutory damages permitted under the causes of action alleged herein, including punitive damages;

G. An Order requiring CVS to pay restitution to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising, or a violation of the UCL, FAL or CLRA, plus pre-and post-judgment interest thereon;

H. An Order awarding costs, expenses, and reasonable attorneys' fees; and

I. Any other and further relief the Court deems necessary, just, or proper.

JURY DEMAND

168. Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: December 18, 2013

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Fax: (619) 564-6665

Attorneys for Plaintiff and the Proposed Class

Exhibit 1


CVS/pharmacy
ULTRA
CoQ-10
100 mg
HEART & MUSCLE HEALTH*
CVS/pharmacy
NEW!
ULTRA
CoQ-10
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HEART & MUSCLE HEALTH*
Beneficial for people taking cholesterol-lowering statin drugs
6x BETTER ABSORPTION†
60 Softgels
2 Month Supply
DIETARY SUPPLEMENT
Did you know that most CoQ-10 is not well absorbed in your body?
CVS/pharmacy® Ultra CoQ-10 uses the patented VESIsorb® technology from Switzerland to achieve over 600% better absorption.
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.


CVS/pharmacy
ULTRA
CoQ-10
100 mg
HEART & MUSCLE HEALTH*
6x BETTER ABSORPTION†
CVS/pharmacy® Ultra CoQ-10 uses the patented VESIsorb® nanocolloidal delivery system from Switzerland.
CoQ-10 ABSORPTION COMPARISON
6x
3x
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6x
1x
RELATIVE PEAK ABSORPTION
CVS/pharmacy ULTRA CoQ-10
REGULAR CoQ-10 SOFTGELS
† Z. Xia-Lui et al. Relative Bioavailability Comparison of Different Coenzyme Q10 Formulations with a Novel Delivery System. Alternative Therapies in Health & Medicine 15(2) 2009, 42-46. Regular CoQ-10 refers to unsolubilized Ubiquinone in oil suspensions in softgels and/or powder-filled capsules/tablets.
VESIsorb® is a registered trademark of SourceOne Global Partners.
part # 23166
#893746
LOT. F12NM09
EXP. 05/14
0 50428 45548 7
DIRECTIONS: As a dietary supplement, take one (1) softgel daily with a meal. For adults only. Consult your doctor before taking any supplement.
Supplement Facts
Serving Size: 1 Softgel
Amount Per Serving %DV
Coenzyme Q-10 100mg ††
†† Daily Value not established
OTHER INGREDIENTS: Gelatin Capsule (Gelatin, Glycerin, Purified Water, Annatto, Titanium Dioxide), Medium Chain Triglycerides, Polysorbate 80, Polyglycerol Esters of Fatty Acids, Citrus Oil Extract (Citrus sinensis, peel), d-alpha Tocopherol.
GUARANTEED: No sugar, salt, yeast, wheat, gluten, milk, preservatives or artificial colors.
KEEP OUT OF REACH OF CHILDREN. For optimal storage conditions, keep in a cool, dry place with the cap tightly closed. Protect from excessive heat or freezing.
TAMPER RESISTANT: DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.
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NEW!
6x Better Absorption†
6x BETTER ABSORPTION†
60 Softgels
2 Month Supply
DIETARY SUPPLEMENT
DIRECTIONS: As a dietary supplement, take one (1) softgel daily with a meal. For adults only. Consult your doctor before taking any supplement.
Supplement Facts
Serving Size: 1 Softgel
Amount Per Serving %DV
Coenzyme Q-10 100mg ††
†† Daily Value not established
OTHER INGREDIENTS: Gelatin Capsule (Gelatin, Glycerin, Purified Water, Annatto, Titanium Dioxide), Medium Chain Triglycerides, Polysorbate 80, Polyglycerol Esters of Fatty Acids, Citrus Oil Extract (Citrus sinensis, peel), d-alpha Tocopherol.
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ULTRA CoQ-10
100 mg

HEART & MUSCLE HEALTH*

6x BETTER ABSORPTION†

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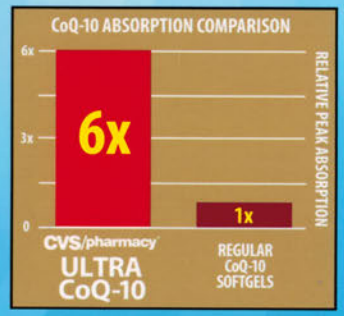

† Zu-Lui et al. Relative Bioavailability Comparison of Different Coenzyme Q10 Formulations with a Novel Delivery System. Alternative Therapies in Health & Medicine 15(2) 2009, 42-46. Regular CoQ-10 refers to unsolubilized Ubiquinone in oil suspensions in softgels and/or powder-filled capsules/tablets.

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ULTRA CoQ-10
100 mg
HEART & MUSCLE HEALTH*

CVS/pharmacy

NEW!

ULTRA CoQ-10
100 mg
HEART & MUSCLE HEALTH*

Beneficial for people taking cholesterol-lowering statin drugs

6x BETTER ABSORPTION†

60 Softgels
2 Month Supply

DIETARY SUPPLEMENT

DIRECTIONS: As a dietary supplement, take one (1) softgel daily with a meal. For adults only. Consult your doctor before taking any supplement.

Supplement Facts
Serving Size: 1 Softgel

Amount Per Serving		%DV
Coenzyme Q-10	100mg	††

†† Daily Value not established

OTHER INGREDIENTS: Gelatin Capsule (Gelatin, Glycerin, Purified Water, Annatto, Titanium Dioxide), Medium Chain Triglycerides, Polysorbate 80, Polyglycerol Esters of Fatty Acids, Citrus Oil Extract (*Citrus sinensis*, peel), d-alpha Tocopherol.

GUARANTEED: No sugar, salt, yeast, wheat, gluten, milk, preservatives or artificial colors.

KEEP OUT OF REACH OF CHILDREN. For optimal storage conditions, keep in a cool, dry place with the cap tightly closed. Protect from excessive heat or freezing.

TAMPER RESISTANT: DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

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Absorption†

Exhibit 2

ORIGINAL RESEARCH

RELATIVE BIOAVAILABILITY COMPARISON OF DIFFERENT COENZYME Q_{10} FORMULATIONS WITH A NOVEL DELIVERY SYSTEM

Zheng-Xian Liu, PhD; Carl Artmann, PhD

Commercial coenzyme Q_{10} (CoQ_{10}, ubiquinone) formulations are often of poor intestinal absorption. The relative bioavailability of CoQ_{10} has been shown in National Institutes of Health–funded clinical trials to be increased by its delivery system. We investigated the bioavailability of a new CoQ_{10} formulation based on a new and patented technology, VESIsorb, with 3 other commercially available CoQ_{10} products, an oil-based formulation and 2 solubilizates. This new CoQ_{10} formulation (commercially branded CoQsource) is a lipid-based formulation that naturally self-assembles on contact with an aqueous phase into an association colloid delivery system (hereafter "colloidal-Q_{10}"). Twenty healthy male and female subjects participated in a double blind, comparative (parallel design), controlled, single-dose (120 mg) bioavailability study. Plasma concentration of CoQ_{10} was determined at baseline and at various intervals after administration over a 24-hour period. To compare bioavailability, maximum concentration (C_{max}) and area under curve from 0 to >10 hours ($AUC_{(0\text{-}10h)}$) were assessed. The kinetic profiles of all CoQ_{10} preparations revealed a 1-peak plasma concentration-time course. Highest C_{max} values were seen after colloidal-Q_{10} administration. Colloidal-Q_{10} not only had the highest plasma concentration levels after 1 hour, but it continued to increase before reaching C_{max} at about 4 hours. The plasma concentration of colloidal-Q_{10} remained well above the levels of the 3 other products throughout the 24-hour period. The relative bioavailability calculated using the $AUC_{(0\text{-}10h)}$ values was also the highest for colloidal-Q_{10}; the $AUC_{(0\text{-}10h)}$ values were 30.6, 6.1, 4.9 and 10.7 µg/ml*h for colloidal-Q_{10}, solubilizate 1, the oil-based formulation, and solubilizate 2, respectively. Differences in C_{max} and AUC between colloidal-Q_{10} and the 3 other formulations were statistically significant. In summary, the data presented suggests that colloidal-Q_{10} improves the enteral absorption and the bioavailability of CoQ_{10} in humans. (*Altern Ther Health Med*. 2009;15(2):#-#.)

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Disclosure

The work was funded by Vesifact AG, Baar, Switzerland, and performed at Phacos GmbH, Schrimpfstr. 49/3, D-82131 Gauting, Germany. Zheng-Xian Liu, PhD, is chief executive officer of GeroNutra and served as a paid consultant to SourceOne Global Partners in the preparation of this manuscript but holds no other financial interest in the products or technologies studied or in either Vesifact or SourceOne. Carl Artmann, PhD, is chief executive officer of Phacos GmbH and served as paid consultants to Vesifact in monitoring and analyzing this study but holds no other financial interest in the products or technologies studied or in either Vesifact or SourceOne.

Coenzyme Q_{10} (CoQ_{10}) plays a key role in mitochondrial cell physiology and is a powerful systemic antioxidant. Its chemical structure is shown in Figure 1. In certain conditions, the body's capacity for adequate CoQ_{10} homeostasis is impaired. In such situations, supplementation with CoQ_{10} has been shown to be beneficial.

Due to its poor solubility in water and its relatively high molecular weight (M_r=863) the oral bioavailability of CoQ_{10}, when administered as a powder, is low.[1,2] In the past several years, extensive efforts have been made to improve the oral bioavailability of CoQ_{10}. Examples of formulation strategies aimed at improving the enteral absorption of CoQ_{10} include oil-based formulations, solubilized formulations, and molecular complexes.[3-10] Several of these strategies have been shown to improve the bioavailability of CoQ_{10} as evidenced by their enhanced plasma CoQ_{10} response.

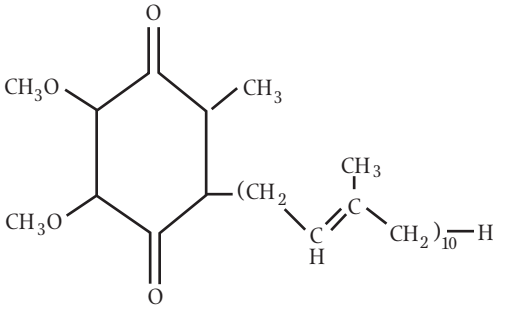

FIGURE 1 Chemical Structure of Coenzyme Q10

It is known that poorly water-soluble supplements (eg, fat-soluble vitamins) are better absorbed when administered after a meal containing fat. One of the reasons for the improved absorption is the enhanced drug solubilization by bile salt-mixed micelles formed from the digestion products of dietary triglycerides (monoglyceride and fatty acids) and bile, a tool developed by nature. The task of naturally formed bile salt-mixed micelles, having a size <10 nm, is to transport the lipophilic molecules through the aqueous environment of the gastrointestinal (GI) tract and across the unstirred water layer to the absorptive epithelium. VESIsorb, a new delivery technology, mimics this natural absorption process to improve bioavailability of poorly water-soluble drugs. The data presented suggest that colloidal-Q_{10}, a CoQ_{10} formulation based on this delivery system, improves the enteral absorption and the bioavailability of CoQ_{10} in humans.

MATERIALS AND METHODS

Design

A double-blind, comparative, controlled (parallel design), single-dose pharmacokinetic study with random assignment of subjects of both sexes was planned. The protocol was approved by the Grosshadern Hospital of Munich ethics commission, and informed consent was obtained from all subjects.

Subjects

Four groups (n=5, n=5, n=5, n=5) of clinically healthy men and women between the ages 18 and 60 years were recruited. Subjects were selected in accordance with the inclusion and exclusion criteria from among the group at Grosshadern Hospital and its facilities. The subjects were informed at the beginning about the nature of the study, its aims, and its execution. The data were acquired and stored in anonymous form.

Inclusion Criteria

- Men and women aged 18 to 60 years
- Clinically healthy, normal body mass index (18.5-25)
- No abnormalities in internal medical history
- No abnormalities in laboratory status
- Subject's agreement to participation in the study

Exclusion Criteria

- Men and women aged under 18 or over 60 years
- Previous history of hematological diseases (eg, known susceptibility to thrombosis)
- Pathological laboratory status (blood count, thrombocytes)
- Medication with vasoactive substances
- Medication affecting coagulation (eg, acetyl salicylic acid, aspirin)
- Medication affecting cholesterol (eg, statins)
- Diabetes
- Skin diseases (acute, chronic, allergic)
- Malignant tumors
- Disorders of heart, kidney, lung, or liver function
- Feverous or infectious diseases
- Alcohol or drug abuse
- Pregnancy or lactation
- Participation in power sports activities or sport activities during the study
- Failure to submit a statement of consent
- Participation in another clinical study within 4 weeks preceding this study or during this study
- Probable noncompliance of the subject; insufficient reliability

Study Preparations

- Product A (colloidal-Q_{10}): 30 mg CoQ_{10} per capsule
- Product B (solubilizate 1): 60 mg CoQ_{10} per capsule
- Product C (oil-based formulation): 30 mg CoQ_{10} per capsule
- Product D (solubilizate 2): 30 mg CoQ_{10} per capsule

Product A was provided by Vesifact AG, Baar, Switzerland. Products B, C, and D are commercially available CoQ_{10} products.

Intervention

Subjects (12 females, 8 males) qualifying for the study on the basis of the inclusion and exclusion criteria were randomized to consume a single oral dose of 120 mg CoQ_{10} in the form of one of the following study preparations:

- 4 capsules of product A (colloidal-Q_{10})
- 2 capsules of product B (solubilizate 1)
- 4 capsules of product C (oil-based formulation)
- 4 capsules of product D (solubilizate 2)

The study preparations were given in the morning before breakfast, on an empty stomach. The taking of blood samples and mealtimes occurred at predetermined regular time intervals (Table 1). For a controlled diet, the same food was eaten among

TABLE 1 Blood Sampling and Mealtimes

Day	Time	Action	Time Elapsed (after CoQ10 intake)
1	07:30-08:00	Blood sample, zero value, empty stomach Administration of 120 mg CoQ10	
	08:00-08:30	Breakfast	
	08:30-09:00	Blood sample	1 h
	09:30-10:00	Blood sample	2 h
	10:30-11:00	Blood sample	3 h
	11:30-12:00	Blood sample	4 h
	12:00-12:30	Lunch	
	12:30-13:00	Blood sample	5 h
	13:30-14:00	Blood sample	6 h
	15:30-16:00	Blood sample	8 h
	17:30-18:00	Blood sample	10 h
	18:00-18:30	Dinner	
2	08:30-09:00	Blood sample, empty stomach	24 h

groups. No other food was eaten (control of compliance).

Analysis of Plasma Samples

Plasma concentration of CoQ_{10} were determined by high-performance liquid chromatography (HPLC) using a Merck/Hitachi HPLC system equipped with an auto sampler (Spectra Physics, Newport Corp, Mountain View, California), a UV detector and an analytical column (Nucleosil RP 18, 5µm, 150 mm x 4 mm, Merck, Whitehouse Station, New Jersey). CoQ_{10} was eluted with acetonitrile and detected at 275 nm.

Statistical Analysis

Data were analysed using GraphPad Prism 3.0 software (GraphPad Software Inc, San Diego, California). For descriptive purposes, the mean and standard deviations of the mean were calculated. The homogeneity of the CoQ_{10} baseline levels at the beginning of the study was statistically evaluated using analysis of variance (ANOVA) and Tukey's multiple comparison test (post hoc test). To assess pharmacokinetic parameters, the area under the observed concentration-time curve above baseline ($AUC_{0\text{-}10h}$) and the observed maximum plasma concentration above baseline (Delta C_{max}) were calculated individually for each volunteer. The AUC and Delta C_{max} were compared after log transformation using ANOVA with the post-hoc Dunnett's multiple comparison test.

A probability level of $P<.05$ was considered to indicate statistical significance.

RESULTS

The pharmacokinetic characteristics of the 4 CoQ_{10} study preparations after a single oral intake of 120 mg CoQ_{10} are summarized in Table 2 and Figure 2. The data show that the mean plasma CoQ_{10} values at baseline were similar in the 4 groups, ranging from 0.75 to 0.90 µg/mL. There was no statistically significant difference between groups A to D (P=.1402). There was a significant increase in CoQ_{10} plasma levels following supplementation in all 4 groups. The kinetic profiles of all 4 preparations revealed a 1-peak plasma concentration-time course. Maximum plasma level was reached between 3 and 5 hours after oral administration. The highest C_{max} values were seen after colloidal-Q_{10} application. Colloidal-Q_{10} had the highest plasma concentration level after 1 hour, and it continued to increase before reaching C_{max} at about 4 hours. The plasma concentration level of colloidal-Q_{10} remained well above the levels associated with the 3 other products throughout the 24-hour period. The relative bioavailability calculated using the $AUC_{(0\text{-}10h)}$ values was also the highest for colloidal-Q_{10}; the $AUC_{(0\text{-}10h)}$ values were 30.6, 6.1, 4.9 and 10.7 µg/ml*h for product A (colloidal-Q_{10}), product B (solubilizate 1), product C (oil-based formulation) and product D (solubilizate 2), respectively. Differences in Delta C_{max} and $AUC_{(0\text{-}10h)}$ between colloidal-Q_{10} and the 3 other formulations were statistically significant. Looking at the $AUC_{(0\text{-}10h)}$, the relative bioavailability of product A was 622% compared to C, 499% to product B, and 286% to product D.

DISCUSSION

The absorption of most drugs depends on 2 processes: (1) the dissolution of the drug in physiological fluids and (2) the absorption process itself (ie, the process by which a drug in solution enters the cells at the absorption site and finally enters general blood circulation). Many drugs are absorbed by passive diffusion (ie, a spontaneous migration of drug molecules from a region of high concentration to a region of low concentration). Other drugs are absorbed by facilitated or active transport, which involves the expenditure of energy by the body. In either event, the dissolution of the drug is the first step in the absorption process unless the drug is administered as a solution. On the

TABLE 2 Pharmacokinetic Parameters of the Four Study Preparations Determined After a Single Oral Intake of 120 mg CoQ_{10}

		Product A (Colloidal-Q10)	Product B (Solubilizate 1)	Product C (Oil-based formulation)	Product D (Solubilizate 2)
Baseline	[µg/mL]				
	Mean	0 90	0.76	0.82	0.75
	SD	0.12	0.11	0.10	0.09
Delta C_{max}	[µg/mL]				
	Mean	5 99	1.68	1.42	2.98
	SD	0.41	0.33	0.39	0.55
C_{max}	[µg/mL]				
	Mean	6.89	2.44	2.24	3.73
	SD	0.51	0.31	0.30	0.49
T_{max}	[h]				
	Mean	4.20	3.40	5.00	4.20
	SD	0.45	0.55	0.00	0.45
$AUC_{(0\text{-}10h)}$	[µg/mL*h]				
	Mean	30.62	6.14	4.92	10.71
	SD	4.24	0.16	1.96	2.35

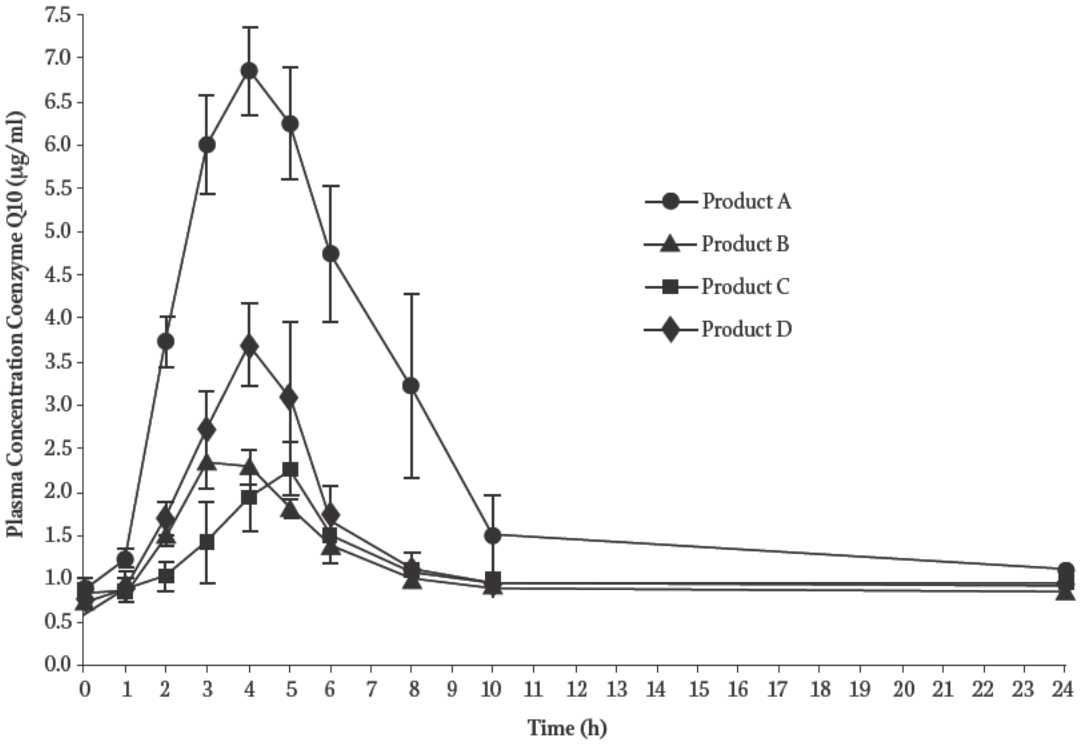

FIGURE 2 Changes in Plasma CoQ10 Concentrations After a Single Oral Intake of 120 mg CoQ10 (n = 20)*

*Product A: colloidal-Q_{10}; product B: solubilizate 1; product C: oil-based formulation; product D: solubilizate 2.

other hand, some drugs are absorbed by the process of pynocytosis or endocytosis, which involves the engulfing of solid particles and the incorporation of such particles into the cellular contents.

To compensate for the poor absorption displayed by many drugs, a formulation may use one or more mechanisms to increase the extent to which the administered drug is absorbed. There are vast numbers of such techniques, which can be grouped into the following broad categories: (1) enhancement of the rate and extent of dissolution and (2) facilitation of an absorption process. Formulating a drug with an oil for the purpose of involving the lymphatic system in the absorption of the drug is an example of the second technique. VESIsorb, the delivery system of colloidal-Q_{10} is an example of the first technique.

VESIsorb was designed to address the poor bioavailability of drugs and natural bioactives like CoQ_{10} exhibiting poor water solubility but high membrane permeability (Biopharmaceutical Classification System: Class II compounds). This delivery system is a lipid-based formulation that self-assembles on contact with an aqueous phase into a colloidal delivery system. The co-administered drug and/or natural bioactive will be solubilized by the in situ formed colloidal system with a mean diameter of <100 nm and a very narrow size distribution as assessed by dynamic laser light scattering using a Zetasizer Nano (Malvern, Worcestershire, United Kingdom). This colloidal solubilization improves the transport of the drug through the aqueous phase of the GI-lumen to the absorptive epithelium, hence its bioavailability. The improvement of oral drug or natural bioactive bioavailability by this technology is broken down into 3 steps: (1) formation of the colloidal delivery system, (2) diffusion across the unstirred water layer, and (3) transfer to the absorption epithelium.

Similar to vitamin E and other lipophilic substances, CoQ_{10} is absorbed, at least partially, by the lymphatic route.[1] Lymphatic absorption involves the following steps: (1) incorporation of CoQ_{10} into lipoproteins/chylomicrons within the enteroyte, (2) secretion of the lipoproteins/chylomicrons from the enterocyte into the lymph vessel, and (3) transport of the lipoproteins/chylomicrons within the lymph vessel to the blood stream. Adequate stimulation of the lipoprotein/chylomicron production is thus of paramount importance for optimal CoQ_{10} absorption by the lymphatic route. This can be achieved by administering CoQ_{10} with or after a meal containing some fat.

CoQ_{10} exhibits non-linear pharmacokinetics (ie, the fraction of a single dose absorbed falls as the dose increases).[11-13] For example, it has been shown that divided dosages (2 x 100 mg) of CoQ_{10} caused a larger increase in plasma levels of CoQ_{10} than a single dose of 200 mg.[12] Larger daily doses of CoQ_{10} should therefore be divided into several doses. Dividing the daily CoQ_{10} dose into several doses will not only maximize the CoQ_{10} absorption, but also reduce the difference between maximal and minimal steady states plasma levels of CoQ_{10}.

In the current study, the posttreatment CoQ_{10} plasma levels of all 4 products are relatively high in comparison to those reported previously. It is difficult to compare the results of this study to other studies: inter-study comparisons are difficult to

make, as variables from food intake to dosing strategy to plasma lipoprotein levels to analytic procedures may affect the results. And there is substantial variation in people's ability to absorb CoQ_{10} in the normal population.[5,14] Additional clinical studies are indicated to verify that the improved absorption with colloidal-Q_{10} correlates with clinical response to treatment.

In the course of the last 25 years of clinical research in treating heart failure of diverse etiology with supplemental CoQ_{10}, it became clear that the initial strategy of normalizing plasma CoQ_{10} status was not effective. Only patients with plasma CoQ_{10} levels >2.5 µg/mL showed significant clinical improvement in heart failure. In fact, therapeutic plasma CoQ_{10} levels are now considered to be > 3.5 µg/ml.[15] Likewise, the pilot trial of CoQ_{10} in patients with Parkinson's disease showed that the benefit was greatest in subjects receiving the highest dosage (1200 mg/d).[16] Thus, a CoQ_{10} formulation exhibiting good CoQ_{10} bioavailability is of great value.

The safety of CoQ_{10}, even at high dosages, is well documented. In particular, a 52-week study revealed no toxicity at a dose of 1200 mg/kg/day,[17] based on which the acceptable daily intake (ADI) for adults weighing 50 kg was estimated to be 600 mg/day. It was also reported in clinical studies of patients with early Parkinson's disease (up to 1200 mg/day for 16 months),[15] Huntington's disease (600mg/day for 30 months),[18] and heart diseases (50-150 mg/day for 3 months)[19] that the frequency of side effects was almost equal to that in the control groups, indicating that the dosage levels examined were within the limits of tolerable intake. In a recent study, the safety profile of CoQ_{10} at high doses for healthy subjects was assessed. CoQ_{10} in capsule form was taken for 4 weeks at doses of 300, 600, and 900 mg/day by a total of 88 adult volunteers. The findings of the study showed that CoQ_{10} was well-tolerated and safe for healthy adults at an intake of up to 900 mg/day.[20] Furthermore, each component of colloidal-CoQ_{10} is Generally Regarded as Safe (GRAS) per the FDA's Code of Federal Regulations (CFR 21) and European regulatory standards, which guarantees the wholesomeness and safety of each ingredient for human consumption. Essentially, it is the FDA's assurance that all ingredients used in food products have undergone toxicological and safety testing to guarantee their safe use in foods.

In summary, this study compared the relative bioavailability of colloidal-Q_{10} with that of 3 commercially available products, 2 CoQ_{10} solubilizates and an oil-based CoQ_{10} formulation after a single oral administration of 120 mg. Our data suggest that the enteral absorption and bioavailability of CoQ_{10} can be enhanced by colloidal-Q_{10} that mimics the naturally occurring mixed micellar transport system of the human body. This also increases the likelihood that this technology can be considered as safe for improving the absorption of drugs with low water solubility. Current research is investigating whether this technology also can be used to improve the absorption of other natural lipophilic actives, such as omega-3, vitamin D, resveratrol, tocotrienols, flavonoids, and gamma-tocopherols.

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Exhibit 3

Mobile phase, System suitability solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Calculate the percentage of impurities in the portion of Ubidecarenone taken:

$$\text{Result} = (r_{T1}/r_{T2}) \times 100$$

r_{T1} = sum of all peak responses, other than that for ubidecarenone

r_{T2} = sum of all peak responses

Acceptance criteria: NMT 1.0%

Procedure 2: Ubidecarenone (2*Z*)-Isomer and Related Impurities

Mobile phase: *n*-Hexane and ethyl acetate (97:3)

System suitability solution: 1 mg/mL of USP Ubidecarenone for System Suitability RS in *n*-hexane

Sample solution: 1 mg/mL of Ubidecarenone in *n*-hexane

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 275 nm

Column: 4.6-mm × 25-cm; packing L3

Flow rate: 2 mL/min

Injection size: 20 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for ubidecarenone (2*Z*)-isomer and ubidecarenone are about 0.85 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between the ubidecarenone (2*Z*)-isomer and ubidecarenone

Analysis

Sample: *Sample solution*

Calculate the percentage of impurities in the portion of Ubidecarenone taken:

$$\text{Result} = (r_{T1}/r_{T2}) \times 100$$

r_{T1} = sum of all peak responses, other than that for ubidecarenone

r_{T2} = sum of all peak responses

Acceptance criteria: NMT 1.0%

Total impurities: NMT 1.5%, obtained from *Chromatographic Purity Procedures 1* and *2*

SPECIFIC TESTS

- **WATER DETERMINATION,** *Method I* ⟨921⟩**:** NMT 0.2%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers.
- **USP REFERENCE STANDARDS** ⟨11⟩

USP Ubidecarenone RS

USP Ubidecarenone Related Compound A RS [coenzyme Q_9]

USP Ubidecarenone for System Suitability RS

Ubidecarenone Capsules

DEFINITION

Ubidecarenone Capsules contain NLT 90.0% and NMT 115.0% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$).

IDENTIFICATION

- **A.** The retention time of the major peak of either *Sample solution 1* or *Sample solution 2* corresponds to that of the *Standard solution*, as obtained in the *Procedure* for *Strength*.

STRENGTH

- **PROCEDURE**

[NOTE—Conduct this test promptly with minimum exposure to actinic light.]

Solvent: *n*-Hexane and dehydrated alcohol (5:2)

Mobile phase: Acetonitrile, tetrahydrofuran, and water (55:40:5)

Standard stock solution: 1.0 mg/mL of USP Ubidecarenone RS in *Solvent*

Standard solution: 40 µg/mL in dehydrated alcohol, from the *Standard stock solution*

System suitability stock solution: 1.0 mg/mL of USP Ubidecarenone Related Compound A RS in *Solvent*. Dilute a portion of this solution with dehydrated alcohol to obtain a concentration of 40 µg/mL.

System suitability solution: *Standard solution* and *System suitability stock solution* (1:1)

Sample solution 1 (for soft gelatin Capsules)**:** Open a number of Capsules equivalent to 200 mg of ubidecarenone, quantitatively transfer the shells and contents to a container, add 100 mL of *Solvent*, and shake by mechanical means for 30 min. Using small portions of *Solvent*, quantitatively transfer this mixture to a 200-mL volumetric flask, and dilute with *Solvent* to volume. Centrifuge a portion of this solution, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol, and dilute with alcohol to volume.

Sample solution 2 (for hard gelatin Capsules)**:** Empty and thoroughly mix the contents of NLT 20 Capsules. Transfer a portion of the powder, equivalent to 100 mg of ubidecarenone, to a 100-mL volumetric flask, add 60 mL of *Solvent*, and shake by mechanical means for 30 min. Dilute with *Solvent* to volume. Centrifuge a portion of this solution, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol, and dilute with alcohol to volume.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 8-mm × 10-cm; packing L1

Flow rate: 2.5 mL/min

Injection size: 15 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

Suitability requirements

Resolution: NLT 2.5 between ubidecarenone and ubidecarenone related compound A, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 2.0% for ubidecarenone, *Standard solution*

Analysis

Samples: *Sample solution 1* or *Sample solution 2*, and *Standard solution*

Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of ubidecarenone from *Sample solution 1* or *Sample solution 2*

r_S = peak area of ubidecarenone from the *Standard solution*

C_S = concentration of USP Ubidecarenone RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of ubidecarenone in *Sample solution 1* or *Sample solution 2* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• **DISINTEGRATION AND DISSOLUTION ⟨2040⟩:** Meet the requirements of the test for *Disintegration*, except where the product is labeled to contain a water-soluble form of ubidecarenone. Capsules labeled to contain a water-soluble form of ubidecarenone meet the requirements for the test for *Dissolution*, as follows.

Medium: Water; 500 mL
Apparatus 2: 75 rpm
Time: 60 min
Standard solution: Dissolve 25 mg of USP Ubidecarenone RS in 1 mL of ethyl ether, and dilute with alcohol to obtain a concentration of 2.5 µg/mL. [NOTE—Use a freshly prepared solution only.]
Sample solution: Dilute with alcohol a volume of the solution under test, previously passed through a suitable filter of 0.45-µm pore size, to obtain a concentration of 2.5 µg/mL of ubidecarenone.
Mobile phase and **Chromatographic system:** Proceed as directed in the *Procedure* for *Strength*, except for *Injection size*.
Injection size: 100 µL
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S \times V \times D/L) \times 100$$

r_U = peak area of ubidecarenone from the *Sample solution*
r_S = peak area of ubidecarenone from the *Standard solution*
C_S = concentration of USP Ubidecarenone RS in the *Standard solution* (mg/mL)
V = volume of *Medium*, 500 mL
D = dilution factor for the *Sample solution*
L = label claim (mg/Capsule)

Tolerances: NLT 75% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) is dissolved.

SPECIFIC TESTS

• **WEIGHT VARIATION ⟨2091⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
• **LABELING:** Where the product contains a water-soluble form of ubidecarenone, this is so stated on the label.
• **USP REFERENCE STANDARDS ⟨11⟩**
USP Ubidecarenone RS
USP Ubidecarenone Related Compound A RS
Coenzyme Q_9.

Ubidecarenone Tablets

DEFINITION

Ubidecarenone Tablets contain NLT 90.0% and NMT 115.0% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Procedure* for *Strength*.

STRENGTH

• **PROCEDURE**

[NOTE—Conduct this test promptly with minimum exposure to actinic light.]
Solvent: *n*-Hexane and dehydrated alcohol (5:2)
Mobile phase: Acetonitrile, tetrahydrofuran, and water (11:8:1)
Standard stock solution: 1.0 mg/mL of USP Ubidecarenone RS in *Solvent*
Standard solution: 40 µg/mL from *Standard stock solution* in dehydrated alcohol
System suitability stock solution: 1.0 mg/mL of USP Ubidecarenone Related Compound A RS in *Solvent*. Dilute a portion of this solution with dehydrated alcohol to obtain a concentration of 40 µg/mL.
System suitability solution: *Standard solution* and *System suitability stock solution* (1:1)
Sample stock solution: Weigh and finely powder NLT 20 Tablets. Transfer a quantity of powder, equivalent to about 100 mg of ubidecarenone, to a 100-mL volumetric flask, add 60 mL of *Solvent*, and shake by mechanical means for 30 min. Dilute with *Solvent* to volume, and mix. Centrifuge a portion of this solution, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, and add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol. Dilute with alcohol to volume, and mix.
Sample solution: Centrifuge a portion of *Sample stock solution*, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol, and dilute with alcohol to volume.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 280 nm
Column: 8-mm × 10-cm; packing L1
Flow rate: 2.5 mL/min
Injection size: 15 µL
System suitability
Samples: *Standard solution* and *System suitability solution*
Suitability requirements
Resolution: NLT 2.5 between ubidecarenone and ubidecarenone related compound A, *System suitability solution*
Tailing factor: NMT 1.5, *Standard solution*
Relative standard deviation: NMT 2.0% for ubidecarenone, *Standard solution*
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of ubidecarenone from the *Sample solution*
r_S = peak area of ubidecarenone from the *Standard solution*
C_S = concentration of USP Ubidecarenone RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of ubidecarenone in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• **DISINTEGRATION AND DISSOLUTION ⟨2040⟩:** Meet the requirements of the test for *Disintegration*, except where the product is labeled to contain a water-soluble form of ubidecarenone. Tablets labeled to contain a water-soluble form of ubidecarenone meet the requirements for the test for *Dissolution*, as follows.

Exhibit 4

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⟨2040⟩ DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS

INTRODUCTION

This general chapter is provided to determine compliance with the disintegration and dissolution standards for dietary supplements where stated in the individual monographs.

For the purposes of this chapter, dietary supplement dosage forms have been divided into three categories: *Vitamin–Mineral Dosage Forms, Botanical Dosage Forms,* and *Dietary Supplements Other Than Vitamin–Mineral and Botanical Dosage Forms. Vitamin–Mineral Dosage Forms* includes articles prepared with vitamins, minerals, or combinations of these dietary ingredients (e.g., USP dietary supplements *Class I* to *Class VI*, described below). *Botanical Dosage Forms* comprises formulations containing ingredients of botanical origin, including plant materials and extracts. *Dietary Supplements Other Than Vitamin–Mineral and Botanical Dosage Forms* encompasses dietary supplements formulated with lawfully recognized dietary ingredients that are different from those pertaining to the two foregoing categories (e.g., amino acids, chondroitin, and glucosamine).

Where a dietary supplement represents a combination of the categories mentioned above, and there is a difference between the requirements for the individual categories, the more stringent requirement applies.

Dissolution testing as described in this chapter is a quality-control tool to enable the performance of dietary supplements to be routinely assessed.

DISINTEGRATION

This test is provided to determine whether dietary supplement tablets or capsules disintegrate within the prescribed time when placed in a liquid medium at the experimental conditions presented below. Compliance with the limits on *Disintegration* stated in the individual monographs for dietary supplements is required except where the label states that the products are intended for use as troches, are to be chewed, or are designed as extended-release dosage forms. Dietary supplements claiming to be extended-release dosage forms must comply with standards other than disintegration to verify that the release of the dietary ingredients from the dosage form is for a defined period of time. Dietary supplements claiming to be extended-release dosage forms shall not be labeled as in compliance with USP unless a USP monograph exists for such product. Determine the type of units under test from the labeling and from observation, and apply the appropriate procedure to 6 or more units.

For purposes of this test, disintegration does not imply complete solution of the unit or even of its active constituent. Complete disintegration is defined as that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus or adhering to the lower surface of the disk, if used, is a soft mass having no palpably firm core.

Apparatus

Apparatus A—Use the *Apparatus* described under *Disintegration* ⟨701⟩ for tablets or capsules that are not greater than 18 mm long. For larger tablets or capsules, use *Apparatus B.*

Apparatus B—The apparatus[1] consists of a basket-rack assembly, a 1000-mL, low-form beaker for the immersion fluid, a thermostatic arrangement for heating the fluid between 35° and 39°, and a device for raising and lowering the basket in the immersion fluid at a constant frequency rate between 29 and 32 cycles per minute through a distance of not less than 53 mm and not more than 57 mm. The volume of the fluid in the vessel is such that at the highest point of the upward stroke the wire mesh remains at least 15 mm below the surface of the fluid and descends to not less than 25 mm from the bottom of the vessel on the downward stroke. At no time should the top of the basket-rack assembly become submerged. The time required for the upward stroke is equal to the time required for the downward stroke, and the change in stroke direction is a smooth transition rather than an abrupt reversal of motion. The basket-rack assembly moves vertically along its axis. There is no appreciable horizontal motion or movement of the axis from the vertical.

Basket-Rack Assembly—The basket-rack assembly consists of three open-ended transparent tubes, each 77.5 ± 2.5 mm long and having an inside diameter of 32.0 to 34.6 mm and a wall 2.0 to 3.0 mm thick; the tubes are held in a vertical position by two plastic plates, each about 97 mm in diameter and 7.5 to 10.5 mm in thickness, with three holes, each about 33 to 34 mm in diameter, equidistant from the center of the plate and equally spaced from one another. Attached to the under surface of the lower plate is 10-mesh No. 23 (0.025-inch) W. and M. gauge woven stainless-steel wire cloth having a plain square weave. The parts of the apparatus are assembled and rigidly held by means of three bolts passing through the two plastic plates. A suitable means is provided to suspend the basket-rack assembly from the raising and lowering device using a point on its axis.

The design of the basket-rack assembly may be varied somewhat provided the specifications for the glass tubes and the screen mesh size are maintained.

Disks—Each tube is provided with a perforated cylindrical disk 15.3 ± 0.15 mm thick and 31.4 ± 0.13 mm in diameter. The disk is made of a suitable, transparent plastic material having a specific gravity of between 1.18 and 1.20. Seven 3.15 ± 0.1-mm holes extend between the ends of the cylinder, one of the holes being through the cylinder axis and the others parallel with it and equally spaced on a 4.2 ± 0.1-mm radius from it. All surfaces of the disk are smooth.[2]

Procedure

Uncoated Tablets—Place 1 tablet in each of the tubes of the basket and, if prescribed, add a disk to each tube. Operate the apparatus, using water or the specified medium as the immersion fluid, maintained at 37 ± 2°. At the end of 30 minutes, lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Plain Coated Tablets—Place 1 tablet in each of the tubes of the basket and, if the tablet has a soluble external sugar coating, immerse the basket in water at room temperature for 5 minutes. Then, if prescribed, add a disk to each tube, and operate the apparatus, using water or the specified medium as the immersion fluid, maintained at 37 ± 2°. At the end of 30 minutes, lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Delayed-Release (Enteric-Coated) Tablets—Place 1 tablet in each of the six tubes of the basket, and if the tablet has a soluble external sugar coating, immerse the basket in water at room temperature for 5 minutes. Then operate the apparatus using simulated gastric fluid TS maintained at 37 ± 2° as the immersion fluid. After

[1] An apparatus and disks meeting these specifications are available from Varian Inc., 13000 Weston Parkway, Cary, NC 27513, or from laboratory supply houses.

[2] The use of automatic detection employing modified disks is permitted where the use of disks is specified or allowed. Such disks must comply with the requirements for density and dimensions given in this chapter.

1 hour of operation in simulated gastric fluid TS, lift the basket from the fluid, and observe the tablets: the tablets show no evidence of disintegration, cracking, or softening. Operate the apparatus, using simulated intestinal fluid TS, maintained at 37 ± 2°, as the immersion fluid for the time specified in the monograph. Lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Buccal Tablets—Apply the test for *Uncoated Tablets*. After 4 hours, lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Sublingual Tablets—Apply the test for *Uncoated Tablets*. At the end of the time limit specified in the individual monograph, all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Hard Shell Capsules—Apply the test for *Uncoated Tablets,* using as the immersion fluid, maintained at 37 ± 2°, a 0.05 M acetate buffer prepared by mixing 2.99 g of sodium acetate trihydrate and 1.66 mL of glacial acetic acid with water to obtain a 1000-mL solution having a pH of 4.50 ± 0.05. Attach a removable wire cloth, as described under *Basket-Rack Assembly,* to the surface of the upper plate of the basket-rack assembly. At the end of 30 minutes, lift the basket from the fluid, and observe the capsules: all of the capsules disintegrate except for fragments from the capsule shell. If 1 or 2 capsules fail to disintegrate completely, repeat the test on 12 additional capsules: not fewer than 16 of the total of 18 capsules tested disintegrate completely.

Soft Shell Capsules—Proceed as directed under *Rupture Test for Soft Shell Capsules.*

Use of Disks—

VITAMIN–MINERAL DOSAGE FORMS—Add a disk to each tube unless otherwise specified in the individual monograph.

BOTANICAL DOSAGE FORMS—Omit the use of disks unless otherwise specified in the individual monograph.

DIETARY SUPPLEMENTS OTHER THAN VITAMIN–MINERAL AND BOTANICAL DOSAGE FORMS—Omit the use of disks unless otherwise specified in the individual monograph.

NOTE—The use of disks for enteric-coated tablets is not permitted.

RUPTURE TEST FOR SOFT SHELL CAPSULES

Medium: water; 500 mL.

Apparatus—Use *Apparatus 2* as described under *Dissolution* ⟨711⟩, operating at 50 rpm.

Time: 15 minutes.

Procedure—Place 1 capsule in each vessel, and allow the capsule to sink to the bottom of the vessel before starting rotation of the blade. Observe the capsules, and record the time taken for each capsule shell to rupture.

Tolerances—The requirements are met if all of the capsules tested rupture in not more than 15 minutes. If 1 or 2 of the capsules rupture in more than 15 but not more than 30 minutes, repeat the test on 12 additional capsules: not more than 2 of the total of 18 capsules tested rupture in more than 15 but not more than 30 minutes.

Change to read:

DISSOLUTION

This test is provided to determine compliance with the *Dissolution* requirements where stated in the individual monograph for dietary supplements, except where the label states that tablets are to be chewed.

See *Dissolution* ⟨711⟩ for description of apparatus used, *Apparatus Suitability Test,* and other related information. Of the types of apparatus described in ⟨711⟩, use the one specified in the individual monograph.

•Soft gelatin capsule preparations of dietary supplements meet the requirements for *Disintegration.*

Official until May 1, 2010

• (RB 1-May-2009)

For hard or soft gelatin capsules and gelatin-coated tablets that do not conform to the dissolution specification, repeat the test as follows. Where water or a medium with a pH of less than 6.8 is specified as the *Medium* in the individual monograph, the same *Medium* specified may be used with the addition of purified pepsin that results in an activity of 750,000 Units or less per 1000 mL. For media with a pH of 6.8 or greater, pancreatin can be added to produce not more than 1750 USP Units of protease activity per 1000 mL.

This nonspecific dissolution is intended to be diagnostic of known technological problems that may arise as a result of coatings, lubricants, disintegrants, and other substances inherent in the manufacturing process. For dosage forms containing botanical extracts, this dissolution measurement allows an assessment of the extent of decomposition of the extract to polymeric or other nondissoluble compounds that may have been produced by excessive drying or other manipulations involved in the manufacture of botanical extracts. The operative assumption inherent in this procedure is that if the index or marker compound(s) or the extract is demonstrated to have dissolved within the time frame and under conditions specified, the dosage form does not suffer from any of the above formulation or manufacturing related problems.

Vitamin–Mineral Dosage Forms

All dietary supplements belonging to USP *Classes II* to *VI,* prepared as tablets or capsules, are subject to the dissolution test and criteria described in this chapter for folic acid (if present) and for index vitamins and index minerals. This test is required because of the importance of the relationship between folate deficiency and the risk of neural tube defects. The accompanying table lists the dissolution requirements for the individual USP classes of dietary supplements. *Class I* dietary supplements are combinations of oil-soluble vitamins for which dissolution standards are not established; hence, dissolution requirements do not apply to the oil-soluble vitamins contained in formulations belonging to *Class IV* or *Class V.* Vitamin–mineral combinations that may not be strictly covered by USP *Class I* to *Class VI* are subject to the dissolution test and criteria specified in the individual monographs.

Dietary Supplements—Vitamin–Mineral Dosage Forms

USP Class	Combination of Vitamins or Minerals Present	Dissolution Requirement
I	Oil-Soluble Vitamins	not applicable
II	Water-Soluble Vitamins	one index vitamin; folic acid (if present)
III	Water-Soluble Vitamins with Minerals	one index vitamin and one index element; folic acid (if present)
IV	Oil- and Water-Soluble Vitamins	one index water-soluble vitamin; folic acid (if present)
V	Oil- and Water-Soluble Vitamins with Minerals	one index water-soluble vitamin and one index element; folic acid (if present)
VI	Minerals	one index element

Unless otherwise stated in the individual monograph, test 6 dosage units for dissolution as directed under *Dissolution* ⟨711⟩.

DISSOLUTION CONDITIONS FOR FOLIC ACID

NOTE—Perform this test under light conditions that minimize photo degradation.

Medium: water; 900 mL. If the units tested do not meet the requirements for dissolution in water, test 6 additional dosage units for dissolution in a medium of 900 mL of 0.05 M pH 6.0 citrate buffer solution, prepared by mixing 9.5 mL of 0.1 M citric acid monohydrate and 40.5 mL of 0.1 M sodium citrate dihydrate in a 100-mL volumetric flask, diluting with water to volume, mixing, and adjusting to a pH of 6.0 by using either 0.1 M hydrochloric acid or 0.1 M sodium hydroxide solution.

Apparatus 1: 100 rpm, for capsules.

Apparatus 2: 75 rpm, for tablets.

Time: 1 hour.

NOTE—Compliance with the dissolution requirements for folic acid does not exempt the product from dissolution testing of the pertinent index vitamin or the corresponding index mineral.

DISSOLUTION CONDITIONS FOR INDEX VITAMINS AND INDEX MINERALS

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 1: 100 rpm, for capsules.

Apparatus 2: 75 rpm, for tablets.

Time: 1 hour.

For formulations containing 25 mg or more of the index vitamin, riboflavin, use the following conditions:

Medium: 0.1 N hydrochloric acid; 1800 mL.

Apparatus 1: 100 rpm, for capsules.

Apparatus 2: 75 rpm, for tablets.

Time: 1 hour.

NOTE—Compliance with dissolution requirements for the pertinent index vitamin or index mineral does not exempt the product from dissolution testing of folic acid, if present.

SELECTION OF INDEX VITAMINS AND INDEX ELEMENTS

Compliance with the dissolution requirements for dietary supplements representing combinations of water-soluble vitamins (*Water-Soluble Vitamins Capsules* and *Water-Soluble Vitamins Tablets*) and combinations of oil- and water-soluble vitamins (*Oil- and Water-Soluble Vitamins Capsules* and *Oil- and Water-Soluble Vitamins Tablets*) is determined by measuring the dissolution of a single index vitamin from the water-soluble vitamins present. Riboflavin is the index vitamin when present in the formulation. For formulations that do not contain riboflavin, pyridoxine is the index vitamin. If neither riboflavin nor pyridoxine is present in the formulation, the index vitamin is niacinamide (or niacin), and in the absence of niacinamide (or niacin), the index vitamin is thiamine. If none of the above four water-soluble vitamins is present in the formulation, the index vitamin is ascorbic acid.

Compliance with the dissolution requirements for dietary supplements representing combinations of minerals (*Minerals Capsules* and *Minerals Tablets*) is determined by measuring the dissolution of only one index element. Iron is the index element when present in the formulation. For formulations that do not contain iron, the index element is calcium. If neither iron nor calcium is present, the index element is zinc, and in the absence of all three of these elements, magnesium is the index element.

Compliance with dissolution requirements for dietary supplements representing combinations of water-soluble vitamins and minerals (*Water-Soluble Vitamins with Minerals Capsules* and *Water-Soluble Vitamins with Minerals Tablets*) and combinations of oil- and water-soluble vitamins and minerals (*Oil- and Water-Soluble Vitamins with Minerals Capsules* and *Oil- and Water-Soluble Vitamins with Minerals Tablets*) is determined by measuring the dissolution of one index water-soluble vitamin and one index element, designated according to the respective hierarchies described above.

PROCEDURES

In the following procedures, combine equal volumes of the filtered solutions of the 6 individual specimens withdrawn, and determine the amount of folic acid or the index vitamin or element dissolved, based on the average of 6 units tested. Make any necessary modifications including concentration of the analyte in the volume of test solution taken. Use the *Medium* for preparation of the Standard solution and dilution, if necessary, of the test solution.

Folic Acid—Determine the amount of $C_{19}H_{19}N_7O_6$ dissolved by employing the procedure set forth in the *Assay for folic acid* under *Oil- and Water-Soluble Vitamins with Minerals Tablets*, in comparison with a Standard solution having a known concentration of USP Folic Acid RS in the same *Medium*.

Niacin or Niacinamide, Pyridoxine, Riboflavin, and Thiamine—Determine the amount of the designated index vitamin dissolved by employing the procedure set forth in the *Assay for niacin or niacinamide, pyridoxine, riboflavin, and thiamine* under *Water-Soluble Vitamins Tablets.*

Ascorbic Acid—Determine the amount of $C_6H_8O_6$ dissolved by adding 10 mL of 1.0 N sulfuric acid and 3 mL of starch TS to 100.0 mL of test solution, and titrating immediately with 0.01 N iodine VS. Perform a blank determination, and make any necessary correction.

Iron, Calcium, Magnesium, and Zinc—Determine the amount of the designated index element dissolved by employing the procedure set forth in the appropriate *Assay* under *Minerals Capsules*.

TOLERANCES

The requirements are met if not less than 75% of the labeled content of folic acid and not less than 75% of the labeled content of the index vitamin or the index element from the units tested is dissolved in 1 hour.

Botanical Dosage Forms

Compliance with dissolution requirements necessitates the testing of 6 dosage units individually, or testing 2 or more dosage units in each of the 6 vessels of the dissolution apparatus, and measuring the dissolution of one or more index/marker compound(s) or the extract specified in the individual monograph.

PROCEDURES

Combine equal volumes of the filtered solutions of the 6 or more individual specimens withdrawn, and use the pooled sample as the test solution. Determine the average amount of index or marker compound(s) or the extract dissolved in the pooled sample by the *Procedure* specified in the individual monograph. Make any necessary modifications, including concentration of the analyte in the volume of the test solution taken. Use the *Medium* for preparation of the Standard solution and dilution, if necessary, of the test solution.

INTERPRETATION

Pooled Sample—Unless otherwise specified in the individual monograph, the requirements are met if the quantities of the index or marker compound(s) or the extract dissolved from the pooled sample conform to the accompanying acceptance table. The quantity, Q, is the amount of dissolved index or marker compound(s) or the extract specified in the individual monograph, expressed as a percentage of the labeled content. The 5%, 15%, and 25% values in the acceptance table are percentages of the labeled content so that these values and Q are in the same terms.

Acceptance Table for a Pooled Sample

Stage	Number Tested	Acceptance Criteria
S_1	6	Average amount dissolved is not less than Q + 10%
S_2	6	Average amount dissolved (S_1 + S_2) is equal to or greater than Q + 5%
S_3	12	Average amount dissolved (S_1 + S_2 + S_3) is equal to or greater than Q

Dietary Supplements Other Than Vitamin–Mineral and Botanical Dosage Forms

Unless otherwise stated in the individual monographs for dietary supplement dosage forms in this category, compliance requires the testing of 6 individual units, measuring the dissolution of the dietary ingredient as the average of the 6 units tested.

PROCEDURES

Combine equal volumes of the filtered solutions of the 6 specimens withdrawn, and use the pooled sample as the test solution. Determine the average amount of dietary ingredient dissolved in the pooled sample by the *Procedure* specified in the individual monograph. Make any necessary modifications, including concentration of the analyte in the volume of the test solution taken. Use the *Medium* for preparation of the Standard solution and for dilution, if necessary, of the test solution.

TOLERANCES

Because of the diversity of chemical characteristics and solubilities of dietary ingredients pertaining to this category, general tolerances cannot be established. See individual monographs for *Tolerances*.

Exhibit 5

Tampa Bay Analytical Research, Inc.
13130 56th Court STE 606 Clearwater, FL 33760 USA
Ph: 727-540-0900 Fax: 727-540-0922

Assay Result Form

Number:	ARF-TM05446	Sample Name:	CoQ10		
Control Number:	TM05446	Sample Lot #:	**#1**		
Customer Name:	Law Offices of J.F.	Address:	**San Diego, CA**		
Date:	11/22/2013	Project #:	PR2124	Version:	2

Analyte	Method Reference	Specification	Result	Date Tested	Notebook Reference
CoQ10 Capsule 1	TBAR-TM-012 Dissolution	NA	**None Detected** Notes :a,b	11/18/2013	TBAR-110-95
CoQ10 Capsule 2		NA	**None Detected** Notes: b		
CoQ10 Capsule 3		NA	**27.9 mg** Notes: c		
CoQ10 Capsule 4		NA	**0.578 mg** Notes: b		
CoQ10 Capsule 5		NA	**None Detected** Notes: b		
CoQ10 Capsule 6		NA	**None Detected** Notes : b		

Notes:

a. Ubidecarenone reference standard: Kaneka lot S376, 99.9% purity

b. No visible rupture observed after 60 minutes

c. Approximate rupture time of 50 minutes

Documentation to support these results is on file at Tampa Bay Analytical Research. All quantitative results are rounded to three (3) significant figures. This product analysis is for the benefit of the client only, and results are applicable only to the test material submitted to Tampa Bay Analytical Research, and can not be applied to any other test material or sample. It is the responsibility of the client to determine the suitability of the information provided in this report for their specific use.

File: \\TBAR-2\Documents (E:)\QualityManual\SOPs\Forms\5.8.01-F2

Written By:

Robert Arce
Quality Assurance Manager

Approved By:

Mark Roman
President

Tampa Bay Analytical Research, Inc.
13130 56th Court STE 606 Clearwater, FL 33760 USA
Ph: 727-540-0900 Fax: 727-540-0922

Assay Result Form

Number:	ARF-TM05447	Sample Name:	CoQ10		
Control Number:	TM05447	Sample Lot #:	**#2**		
Customer Name:	Law Offices of J.F.	Address:	**San Diego, CA**		
Date:	11/22/2013	Project #:	PR2124	Version:	2

Analyte	Method Reference	Specification	Result	Date Tested	Notebook Reference
CoQ10 Capsule 1	TBAR-TM-012 Dissolution	NA	**None Detected** Notes :a, b	11/18/2013	TBAR-110-95
CoQ10 Capsule 2		NA	**None Detected** Notes: b		
CoQ10 Capsule 3		NA	**27.6 mg** Notes: c		
CoQ10 Capsule 4		NA	**0.720 mg** Notes: b		
CoQ10 Capsule 5		NA	**0.564 mg** Notes: b		
CoQ10 Capsule 6		NA	**None Detected** Notes: b		

Notes:

a. Ubidecarenone reference standard: Kaneka lot S376, 99.9% purity

b. No visible rupture observed after 60 minutes

c. Approximate rupture time of 50 minutes

Documentation to support these results is on file at Tampa Bay Analytical Research. All quantitative results are rounded to three (3) significant figures. This product analysis is for the benefit of the client only, and results are applicable only to the test material submitted to Tampa Bay Analytical Research, and can not be applied to any other test material or sample. It is the responsibility of the client to determine the suitability of the information provided in this report for their specific use.

File: \\TBAR-2\Documents (E:)\QualityManual\SOPs\Forms\5.8.01-F2

Written By:

Robert Arce
Quality Assurance Manager

Approved By:

Mark Roman
President

Exhibit 6

YAKUGAKU ZASSHI 127(8) 1251—1254 (2007)

—Regular Articles—

Improvement in Intestinal Coenzyme Q10 Absorption by Food Intake

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Coenzyme Q10 (CoQ10) is widely consumed as a food supplement because of its recognition as an important nutrient in supporting human health. Absorption of compounds from the gastrointestinal tract is one of the important determinants of oral bioavailability. However, the absorption of dietary CoQ10 is slow and limited due to its hydrophobicity and large molecular weight. The absorption of orally applied compounds can be enhanced by interactions with food or food components. Thus, we investigated the effect of food intake on the absorption of CoQ10 after oral supplementation. In this study, we demonstrated that food intake enhanced the intestinal absorption of CoQ10. In order to improve intestinal absorption of CoQ10 after oral supplementation, we developed an emulsion formulation. Intestinal absorption of CoQ10 after administration of the emulsion formulation was also enhanced by food intake. Moreover, the peak concentration and the extent of absorption after administration of the emulsion formulation were greater than those after administration of a suspension formulation. It is possible that administration of CoQ10 in an emulsion formulation enhances the pharmacological effects of CoQ10.

Key words——coenzyme; bioavailability; food; emulsion

INTRODUCTION

Coenzyme Q10 (CoQ10) functions in its reduced form as an antioxidant, protecting biological membranes and serum LDL from lipid peroxidation.[1–3] CoQ10 is a ubiquitous compound vital to a number of activities related to energy metabolism. Humans, by nature, have the ability to produce CoQ10. However, this ability starts to decline at the age of 20 years and the amount of CoQ10 in the body decreases rapidly after the age of 40 years.[4] The importance of CoQ10 for living organisms has been illuminated by reports of genetic disorders in which CoQ10 synthesis is impaired.[5]

CoQ10 is widely consumed as a food supplement because of its recognition as an important nutrient in supporting human health. The rationale for the use of CoQ10 as a therapeutic agent in cardiovascular and degenerative neurologic and neuromuscular diseases is based on its fundamental role in mitochondrial function and cellular bioenergetics. There are data supporting the therapeutic value of CoQ10 as an adjust to standard medical therapy in cardiovascular diseases.[6–8] There are also data indicating beneficial effects of CoQ10 in patients with diabetes and cancer.[9,10]

Absorption of compounds from the gastrointestinal tract is one of the important determinants of oral bioavailability. However, the absorption of dietary CoQ10 is slow and limited due to its hydrophobicity and large molecular weight.[11] The absorption of orally applied compounds can be enhanced by interactions with food or food components. Thus, we focused on the effect of food intake on the absorption of CoQ10 after oral supplementation. However, there are various effects of food intake on drug absorption. Food intake has been found to enhance absorption in some cases but to weaken absorption in other cases. The aim of this study was to determine the influence of food intake on the pharmacokinetics of CoQ10 after oral administration. In order to improve intestinal absorption of CoQ10 after oral supplementation, we developed an emulsion formulation. We investigated the effect of food intake on the pharmacokinetics of CoQ10 after oral administration of the emulsion formulation.

MATERIALS AND METHODS

Chemicals CoQ10 powder and emulsion formulation of CoQ10 were kindly supplied by Kougen

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Co., Ltd. (Shizuoka, Japan: manufactured by Zhejiang Medicine Co., Ltd. Xinchang Pharmaceutical Factory). All other reagents were of the highest grade available and used without further purification.

Animals Male Wistar rats, aged 7 to 9 weeks (200–250 g in weight), were obtained from Jla (Tokyo, Japan). The housing conditions were the same as those described previously.[12] The rats were housed at least 1 week at 23±3℃ and 50±10% relative humidity and were maintained on a 12 h light/dark cycle. During the acclimatization the rats were allowed free access to food and water. The experimental protocols were reviewed and approved by the Hokkaido University Animal Care Committee in accordance with the "Guide for the Care and Use of Laboratory Animals".

***In vivo* Administration Study** To determine the effect of food-intake on the absorption of CoQ10, the rats were divided into two groups: a control group in which rats were fasted for 14 h prior to the experiments and a food-intake group in which rats were allowed free access to food. Rats were anaesthetized by an intraperitoneal (*i.p.*) injection of 50 mg/kg sodium pentobarbital. The rats were fixed after the operation. CoQ10 was administered in a suspension or emulsion (25 mg/kg body weight). Sequential blood samples were obtained from the femoral vein. Plasma was obtained by centrifugation (850 x g for 10 min).

***In situ* Absorption Study** Rats were fasted for 14 h prior to the experiments and a food-intake group in which rats were allowed free access to food. Rats were anaesthetized by an *i.p.* injection of 50 mg/kg sodium pentobarbital. The rats were fixed after the operation. A small midline incision was made in the abdomen. A 10-cm-long loop of the jejunum was identified and ligated at both ends. Five hundred μl of CoQ10 (2.5 mg/ml of CoQ10) was administered directly into the loops. Intestinal contents were taken from the loops at 30 min after injection.

Analytical Procedures Coenzyme Q10 was determined by HPLC using absolute calibration curve method. HPLC method and sample processing were modified as described by Lu et al.[13] with minor modification. Two hundred μl of CoQ10 solutions in absolute methanol was added to 100 μl of plasma to prepare the calibration curves. One hundred μl of specimens was diluted three fold with methanol. After vortexing, the sample was extracted with 1 ml of n-hexane. After shaking the mixture vigorously, the sample was centrifuged at 2000 x g for 5 min at 4℃. Nine hundred μl of the organic layer was evaporated to dryness under a gas stream. The residue was redissolved in 100 μl of mobile phase for HPLC injection. The concentration of CoQ10 was determined using an HPLC system equipped with a JASCO 880-PU pump and a 870-UV UV-vis detector. The column was a GL Science ODS-2 (5 μm in particle size, 4.6 mm in inside diameter x 250 mm). A mobile phase containing 2-propanol/methanol/THF (55/39/6) was used. The column temperature and flow rate were 40℃ and 1.0 ml/min, respectively. The wavelength for detection was 275 nm. Forty μl of sample was injected into the HPLC system. We used CoQ10 powder for a standard solution. Calibration curve was constructed in the concentration range of 0–2.4 mg/l. The absolute recoveries of CoQ10 were estimated by comparison of the area increments after extraction from plasma to that obtained after direct injection of a solution. CoQ10 extraction yielded significant recoveries (65 %) and showed the best reproducibility.

Data Analysis A two-compartment model was fitted to the plasma data using Origin 6.1J. The parameters in this model are D (dose of administration), k_{21} (rate constant for transfer from the peripheral to central compartment, and V (volume of distribution). The area under the plasma concentration-curve (AUC) was estimated by the trapezoidal rule. Student's t-test was used for statistical analysis, and a value of $p<0.05$ was considered significant.

RESULTS AND DISCUSSION

CoQ10 is a ubiquitous compound vital to a number of activities related to energy metabolism. Since dysfunctional energy metabolism has been shown to be a factor contributing to a number of conditions, dietary supplementation of CoQ10 has been used in the treatment of cardiac, neurologic, oncologic and immunologic disorders.[14] However, CoQ10 is taken up from the intestine at a low rate.[11] Since the absorption of orally applied compounds can be enhanced by the presence of food components, we focused on the effect of food intake on absorption of CoQ10.

In the first part of this study, we investigated the effect of food intake on plasma concentration of CoQ10 after single oral administration of CoQ10 in a suspension. Figure 1 shows the plasma concentration of CoQ10 after oral administration. Pharmacokinetic parameters are listed in Table 1. The time to reach

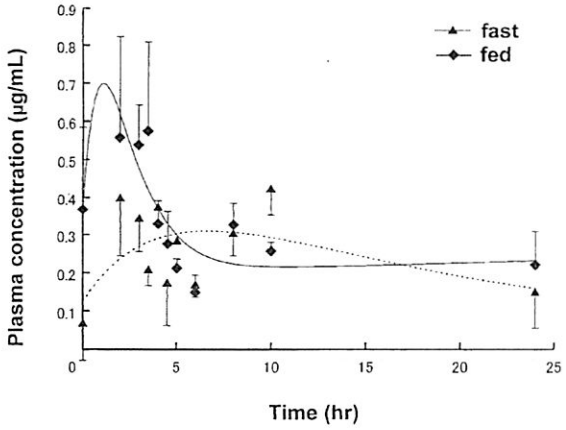

Fig. 1. Time Profile of Plasma Concentration of CoQ10 after Oral Administration (25 mg/kg Body Weight) of a Suspension

Each point represents the mean with S.E. of 3–6 measurements.

Table 1. Effect of Food Intake on Kinetic Parameters of CoQ10 after Oral Administration of a Suspension

	C_{max} (μg/ml)	T_{max} (h)	AUC (μg h/ml)
Fast	0.31	3.64	3.99
Fed	0.70	1.13	6.86

maximum (T_{max}) in the food-intake group was three-times shorter than that in the control group. This finding suggests that intestinal absorption of CoQ10 is 3-fold faster with food intake. Moreover, the peak concentration (C_{max}) and AUC of the food-intake group were almost 2-fold greater than those of the control group. These results suggest that food intake enhanced the intestinal absorption of CoQ10.

Although the mechanism of uptake of CoQ10 has not been studied, solubility of compounds is one of the most critical issues. The use of a lipid-based formulation seems promising as a strategy to overcome the problem of poor solubility.[15,16] We therefore tried to improve the intestinal absorption of CoQ10 by using an emulsion formulation. In the second part of this study, we investigated the intestinal absorption of test formulations of CoQ10 in an *in situ* loop study. The intestinal absorption of CoQ10 is shown in Fig. 2. The residual amount of CoQ10 after administration in suspension was almost the same as the amount of CoQ10 administrated. This finding indicated that the absorption of CoQ10 after administration in a suspension is poor. The residual amount of CoQ10 after administration in an emulsion formulation was significantly smaller than that after administration in a suspension. This result indicated that the absorption of CoQ10 was improved by using the emulsion formulation.

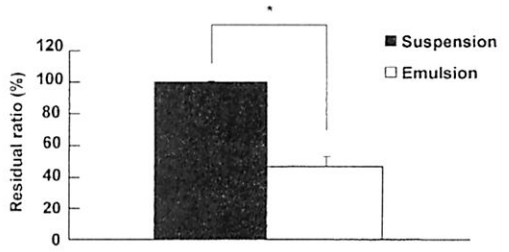

Fig. 2. Residual Ratio of CoQ10 in the Intestinal Loop

CoQ10 (1.25 mg) was administered into the loop. Intestinal contents were taken from the loops at 30 min after injection. Each column represents the mean with S.E. of 3 measurements. $^{*}p<0.05$, significantly different.

The above-described findings indicated the possibility that absorption of CoQ10 can be improved by using both an emulsion formulation and food intake. In the last part of this study, we therefore investigated the effect of food intake on the intestinal absorption of an emulsion formulation of CoQ10. Figure 3 shows the plasma concentration of CoQ10 after oral administration of the emulsion formulation. Pharmacokinetic parameters are listed in Table 2. T_{max} of the food-intake group was two-times shorter than that of the control group. This finding suggests that intestinal absorption of CoQ10 is 2-fold faster with food intake. Moreover, C_{max} and AUC of the food-intake group were 5-fold and 2-fold greater than those of the control group, respectively. These results suggest that intestinal absorption of CoQ10 after administration of the emulsion formulation was also enhanced by food intake. T_{max}, C_{max} and AUC after administration of the emulsion formulation in the food-intake group were three-times smaller, eight-times larger and five-times larger, respectively, than those after administration of the suspension in the control group. These findings suggest that the development of appropriate dosing regimens using emulsion formulation of CoQ10 with food supplementation may offer improved pharmacological effects. In addition to food components, bile acids are also known to enhance the intestinal absorption of poorly water-soluble drugs. Food intake stimulates biliary excretion of bile acids. This absorption process is carried out by micelles. The formation of micelles and incorporation of poorly water-soluble drugs into micelles are thought to be important for absorption. Since bile

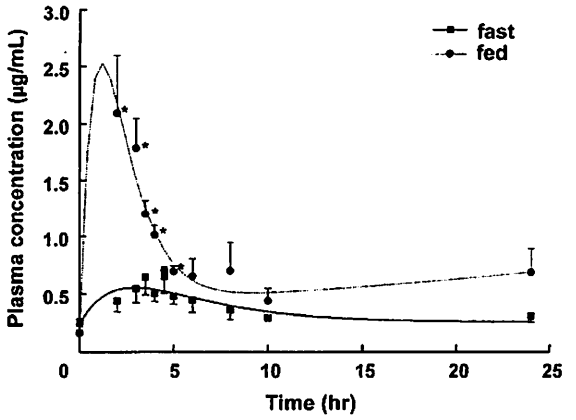

Fig. 3. Time Profile of Plasma Concentration of CoQ10 after Oral Administration (25 mg/kg Body Weight) of an Emulsion Formulation

Each point represents the mean with S.E. of 3 measurements. *$p<0.05$, significantly different.

Table 2. Effect of Food Intake on Kinetic Parameters of CoQ10 after Oral Administration of an Emulsion Formulation

	C_{max} (μg/ml)	T_{max} (h)	AUC (μg h/ml)
Fast	0.55	2.91	8.50
Fed	2.52	1.21	19.3

acids are essential for micelle formation, they are needed for the intestinal absorption of poorly water-soluble drugs. With regard to the effect of food intake on the plasma concentration of CoQ10 after oral administration, it is possible that some food components or bile acids play important roles in the intestinal absorption of CoQ10.

In summary, we have demonstrated that a higher plasma concentration of CoQ10 was achieved by using an emulsion formulation and food intake. Beneficial effects of CoQ10 supplementation have been observed in both experimental models and human patients.[17,18] It is possible that administration of CoQ10 in an emulsion formulation enhances the pharmacological effects of CoQ10. Further studies are needed to assess the pharmacological effects of CoQ10 using an emulsion formulation and to elucidate the mechanisms by which food components or bile acids increase the bioavailability of CoQ10. Such investigations will provide important information for improving the pharmacological effects of CoQ10.

Acknowledgements We thank Kougen Co., Ltd. for providing CoQ10 and supporting this study.

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Exhibit 7

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Counsel for Plaintiff and the Proposed Classes

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

LEO HARRIS, on behalf of himself, all others similarly situated and the general public,

Plaintiff,

v.

CVS PHARMACY, INC.,

Defendant.

CONSUMERS LEGAL REMEDIES ACT VENUE AFFIDAVIT [CCP § 1780(d)]

I, Leo Harris, declare as follows:

1. I am the Plaintiff in this action. I make this affidavit as required by California Civil Code § 1780(d).

2. The Complaint in this action is filed in a proper place for the trial of this action because defendant is doing business in this county.

3. The Complaint in this action is further filed in a proper place for the trial of this action because the transactions that are the subject of the action occurred in this county.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 9 day of December, 2013, at Highland, California.

Leo Harris

Leo Harris

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES JUDGES

This case has been assigned to District Judge Ronald S.W. Lew and the assigned Magistrate Judge is Alicia G. Rosenberg .

The case number on all documents filed with the Court should read as follows:

5:13CV2329 RSWL AGRx

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge.

Clerk, U. S. District Court

December 18, 2013
Date

By J.Prado
Deputy Clerk

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

☐ Western Division
312 N. Spring Street, G-8
Los Angeles, CA 90012

☒ Southern Division
411 West Fourth St., Ste 1053
Santa Ana, CA 92701

☐ Eastern Division
3470 Twelfth Street, Room 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I. (a) PLAINTIFFS (Check box if you are representing yourself ☐)

LEO HARRIS, on behalf of himself, all others similarly situated, and the general public

DEFENDANTS (Check box if you are representing yourself ☐)

CVS PHARMACY, INC.

(b) County of Residence of First Listed Plaintiff San Bernadino
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorneys (*Firm Name, Address and Telephone Number*) If you are representing yourself, provide the same information.

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Ronald A. Marron (SBN 175650)
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651 Arroyo Drive, San Diego, CA 92103
619-696-9006

Attorneys (*Firm Name, Address and Telephone Number*) If you are representing yourself, provide the same information.

II. BASIS OF JURISDICTION (Place an X in one box only.)

- ☐ 1. U.S. Government Plaintiff
- ☒ 3. Federal Question (U.S. Government Not a Party)
- ☐ 2. U.S. Government Defendant
- ☐ 4. Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES-For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☒ 1. Original Proceeding ☐ 2. Removed from State Court ☐ 3. Remanded from Appellate Court ☐ 4. Reinstated or Reopened ☐ 5. Transferred from Another District (Specify) ☐ 6. Multi-District Litigation

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☒ Yes ☐ No (Check "Yes" only if demanded in complaint.)

CLASS ACTION under F.R.Cv.P. 23: ☒ Yes ☐ No ☒ **MONEY DEMANDED IN COMPLAINT:** $ To be determined

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
15 U.S.C. §§ 2301 et seq.; Breach of Express and Implied Warranties, Violation of Magnuson-Moss Warranty Act; Violations of California and Rhode Island Consumer Protection Statutes

VII. NATURE OF SUIT (Place an X in one box only).

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/Etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Org.
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Info. Act
- ☐ 896 Arbitration
- ☐ 899 Admin. Procedures Act/Review of Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loan (Excl. Vet.)
- ☐ 153 Recovery of Overpayment of Vet. Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment

REAL PROPERTY CONT.
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Fed. Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury-Med Malpratice
- ☐ 365 Personal Injury-Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accomodations
- ☐ 445 American with Disabilities-Employment
- ☐ 446 American with Disabilities-Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus/Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Ret. Inc. Security Act

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405 (g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405 (g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

EDCV13-2329

FOR OFFICE USE ONLY: Case Number:

VIII. VENUE: Your answers to the questions below will determine the division of the Court to which this case will most likely be initially assigned. This initial assignment is subject to change, in accordance with the Court's General Orders, upon review by the Court of your Complaint or Notice of Removal.

Question A: Was this case removed from state court? ☐ Yes ☒ No If "no, " go to Question B. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX.	STATE CASE WAS PENDING IN THE COUNTY OF:	INITIAL DIVISION IN CACD IS:
	☐ Los Angeles	Western
	☐ Ventura, Santa Barbara, or San Luis Obispo	Western
	☐ Orange	Southern
	☐ Riverside or San Bernardino	Eastern

Question B: Is the United States, or one of its agencies or employees, a party to this action? ☐ Yes ☒ No If "no, " go to Question C. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX.	If the United States, or one of its agencies or employees, is a party, is it:		INITIAL DIVISION IN CACD IS:
	A PLAINTIFF? Then check the box below for the county in which the majority of DEFENDANTS reside.	A DEFENDANT? Then check the box below for the county in which the majority of PLAINTIFFS reside.	
	☐ Los Angeles	☐ Los Angeles	Western
	☐ Ventura, Santa Barbara, or San Luis Obispo	☐ Ventura, Santa Barbara, or San Luis Obispo	Western
	☐ Orange	☐ Orange	Southern
	☐ Riverside or San Bernardino	☐ Riverside or San Bernardino	Eastern
	☐ Other	☐ Other	Western

Question C: Location of plaintiffs, defendants, and claims? (Make only one selection per row)	A. Los Angeles County	B. Ventura, Santa Barbara, or San Luis Obispo Counties	C. Orange County	D. Riverside or San Bernardino Counties	E. Outside the Central District of California	F. Other
Indicate the location in which a majority of plaintiffs reside:	☐	☐	☐	☒	☐	☐
Indicate the location in which a majority of defendants reside:	☐	☐	☐	☐	☒	☐
Indicate the location in which a majority of claims arose:	☐	☐	☐	☒	☐	☐

C.1. Is either of the following true? If so, check the one that applies:

☐ 2 or more answers in Column C

☐ only 1 answer in Column C and no answers in Column D

Your case will initially be assigned to the SOUTHERN DIVISION.
Enter "Southern" in response to Question D, below.

If none applies, answer question C2 to the right. →

C.2. Is either of the following true? If so, check the one that applies:

☒ 2 or more answers in Column D

☐ only 1 answer in Column D and no answers in Column C

Your case will initially be assigned to the EASTERN DIVISION.
Enter "Eastern" in response to Question D, below.

If none applies, go to the box below. ↓

Your case will initially be assigned to the WESTERN DIVISION.
Enter "Western" in response to Question D below.

Question D: Initial Division?	INITIAL DIVISION IN CACD
Enter the initial division determined by Question A, B, or C above: →	Eastern

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

IX(a). IDENTICAL CASES: Has this action been previously filed **in this court** and dismissed, remanded or closed? ☒ NO ☐ YES

If yes, list case number(s): _____

IX(b). RELATED CASES: Have any cases been previously filed **in this court** that are related to the present case? ☒ NO ☐ YES

If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply)

- ☐ A. Arise from the same or closely related transactions, happenings, or events; or
- ☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
- ☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
- ☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

X. SIGNATURE OF ATTORNEY (OR SELF-REPRESENTED LITIGANT): _____ DATE: December 18, 2013

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet).

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405 (g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))