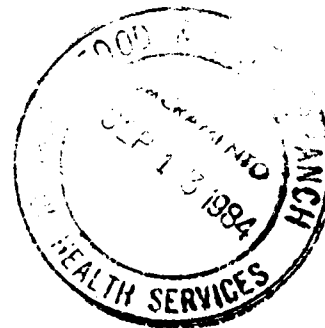


DEPARTMENT OF HEALTH SERVICES

714/744 P STREET
SACRAMENTO, CA 95814
(916) 445-2263



January 18, 1983



Ms. Joal Steed, Manager.
General Nutrition Center
Suite 463, Vintage Fair Mall
Modesto, CA 95356

Dear Ms. Steed:

On December 10, 1982, an embargo was placed by an investigator from this office on materials described as follows:

620/30 tablet bottles of "Advantage" Starch Blockers
5/100 tablet bottles of "Advantage" Starch Blockers
11/6 oz. packages of "Advantage" Starch Blocker Sprinkles.

We believe these materials to be in violation of at least the following:

Section 26460, California Health & Safety Code
Section 26461, California Health & Safety Code
Section 26462, California Health & Safety Code
Section 26534, California Health & Safety Code
Section 26651, California Health & Safety Code
Section 26652, California Health & Safety Code
Section 17200, California Business & Professions Code
Section 17500, California Business & Professions Code.

Please advise me within 30 days of receipt of this letter whether you will voluntarily and at your cost destroy these materials under our supervision. After destruction, you will be provided with a record of the destroyed materials. Instead, you may offer an alternative plan for correcting the alleged violations, by such means as reprocessing and reshipment to the manufacturer.

If we do not hear from you within 30 days, we will commence proceedings for condemnation of the materials, at your expense, by Court Order.

I remind you that these materials may not be removed, sold, or disposed of without permission of this Department.

If you have any questions, please contact Mr. Richard D. Penrose, Regional Administrator, 1220 S Street, Sacramento, CA 95814, (916) 445-6921.

Sincerely,

Actual VC&D Report & Form is in Firm File — Drug Program

C. F. Bryson, Chief
Food and Drug Branch

cc: Mr. Penrose

1/27
stockton
ESP

FDA Enforcement Report 5/12/85

Code: All units identified with manufacturer's name (SVGH) and address
Manufacturer: St. Vincent's General Hospital (SVGH), Leadville, Colorado
Recalled by: Intermountain Plasma, Inc., Grand Junction, Colorado, by telephone May 1, 1985 and by letter May 2, 1985. Firm initiated recall ongoing
Distribution: Florida, New York
Quantity: Approximately 156 units were distributed
Reason: Plasma was salvaged from therapeutic bleedings whose donors did not qualify as a source of whole blood; labeled as nonreactive for hepatitis B surface antigen (HBsAg) when, in fact, it had not been tested for HBsAg.

Product: Recovered Plasma, Recall #B-019-5
Code: Unit #06GK05787
Manufacturer: American Red Cross Blood Services, Los Angeles, California
Recalled by: Manufacturer, by telephone March 15, 1985. Firm initiated recall complete
Distribution: California
Quantity: 1 unit distributed and destroyed
Reason: The plasma was recovered from a unit of Whole Blood which tested reactive for hepatitis B surface antigen (HBsAg); the plasma was labeled as HBsAg nonreactive and shipped for further manufacturing use.

Recall Notices

CLASS III

Product: Appetite Control Factor with CCK (cholecystokinin), 1000 mg. Advantage Supplements brand, an OTC product in 56 and 112 tablet bottles, Recall #D-408-5
Code: All codes
Manufacturer: General Nutrition Corporation, Greenville, South Carolina
Recalled by: General Nutrition Corporation, Pittsburgh, Pennsylvania, by letter April 26, 1985. Firm initiated recall ongoing
Distribution: Nationwide
Quantity: Firm estimates none remains on market
Reason: Product is a new drug marketed without an approved New Drug Application.

DRUGS CLASS III - CONTINUED:

Product: Life Expander brand Fat Fighter with DHEA (dehydroepiandrosterone) 500 mg. tablets, in 50 and 100 tablet bottles, Recall #D-407-5
Code: All codes
Manufacturer: General Nutrition Corporation, Greenville, South Carolina
Recalled by: General Nutrition Corporation, Pittsburgh, Pennsylvania, by

CONSENT AGREEMENTS

The mail order activities of the businesses listed below received attention with respect to alleged violations of Title 39, U.S. Code, Section 3005, False Representation Statute, based on representations made in their advertisements. The firms agreed to the following:

- A. Without admitting the falsity of their advertisements they agreed that the alleged false representations may be reasonably construed by a normal reading of the advertisement.
- B. That the use of this promotional material has been permanently discontinued and will not be resumed directly or indirectly under any other name, address, corporation or other device.
- C. That advertisements making representations similar to the representations alleged will never again be used in the sale of the same or similar product.

1. GENERAL NUTRITION CORP.
418 Wood Street
Pittsburgh, PA
Subject: Medical—Reducing (Model-Etts)
2. VANGAULT LABS
P. O. Box 851
Bradenton, FL 33506
Subject: Formula-55
3. CASINO DE NASIS
256 S. Robertson
Beverly Hills, CA 90211
Subject: Medical- "Stamina-Stay Hard"

Summer 1980



Philadelphia District to be infested by rodents, at North Pole Cold Storage, Pittsburgh.

Seizure of vitamin C tablets valued at \$4,000 retail was made by the Government at General Nutrition Corp., Pittsburgh, and a consent decree has been entered providing for their destruction. FDA's Philadelphia District charged that labeling of the tablets, which contained bioflavonoids, made false and misleading nutritional claims.

REGION IV

An Atlanta food company and its senior vice president were both fined \$1,000 on each of eight counts for a total of \$16,000 after pleading guilty to holding food products contaminated with rodent hair, excreta pellets, and rodent urine and with maintaining a rodent-infested warehouse.

Judge Newall Edenfield of the U.S. District Federal Court, Northern District, Atlanta, imposed the maximum fines on Alterman Foods, Inc., Atlanta, and Max C. Alterman, senior vice president, who was also placed on probation for 2 years. Sidney Schuman, director of warehousing for the company, was placed on 2 years probation without supervision or fine after pleading guilty. At arraignment all had offered pleas of nolo contendere, but these were refused by Judge Edenfield. The company has a 10-year history of insanitary conditions. The terms of the probation were set by the court based on recommendations requested from FDA.

The warehouse violations that resulted in the court actions were discovered by P. Wayne Moy, **Atlanta District** consumer safety officer.

A Florida company initiated a voluntary recall of illegal diethylstilbestrol (DES) injectible doses for animals and later destroyed a recalled quantity after an inspection of a company establishment in Ocala by the Atlanta District's Orlando Section revealed the company was distributing the drug throughout Florida. FDA has withdrawn approval of New Animal Drug Applications for all DES injectibles.

The Florida distributor, Aid Laboratories of North Florida, has outlets in Ocala, Jacksonville, Tampa, and Okeechobee, and home offices in Boca Raton. Marie S. Bendeck, consumer safety officer, Orlando Section, witnessed the company's destruction of six boxes of the product, each containing a dozen vials of the DES. Atlanta District said the manufacturer, Chemvet Laboratories, Kansas City, Missouri, had not effected a recall of the product.

A company at Washington, North Carolina, Ted Day, Inc., voluntarily destroyed 8,000 pounds of crabs after consumer safety officers from the Atlanta District's Raleigh Resident Post found the company was processing decomposed crabs. FDA's Baltimore District had collected official samples of a company shipment prior to the inspection.

About 750 pounds of various potato products was destroyed voluntarily by Daffin Mercantile Co., Inc., Marianna, Florida, and an additional 3,320 pounds intended for human use was converted to animal feeds after an inspection of the company by FDA's Atlanta District found widespread insect infestation on the premises.

REGION V

Through the cooperative efforts of Indiana and Ohio State authorities and Cincinnati and Detroit Districts, milk contaminated by pesticidal chemicals was detected and removed from food channels. **Cincinnati District** originally detected the pesticides in a sample of milk collected at a Cincinnati dairy. Detroit District and Indiana State authorities confirmed the finding of heptachlor epoxide and dieldrin.

Two Indiana dairy farms were pinpointed as being the producers of the milk contaminating the bulk shipment. The Indiana Division of Dairy Products, Indiana State Board of Health, has embargoed the milk of each dairy and it is being dumped. They are maintaining surveillance over production until milk from both producers is free of pesticide residues.

Allen County Food Distributors, a partnership at Fort Wayne, Indiana, and its two partners were fined \$3,000 for operating an insanitary warehouse infested by insects. The partners, John Schmitz and Max T. Schmitz, were sentenced to 1 year in jail, which was suspended pending a successful completion of 1-year probationary period. The charges were brought by FDA's **Detroit District** after an inspection of the company by the Fort Wayne Resident Post.

Judge Jesse Eschbach of the U.S. District Court for Northern Indiana, Fort Wayne, noted the company had also been prosecuted in 1964 for operating an insect-infested warehouse. He told the partners to either comply with the law or get out of business, and stated that if they were found guilty of adulterating food again, they would go to prison.

REGION VI

Two Texas food companies and their principals have been fined and suspended jail sentences imposed in one case on charges brought by FDA's **Dallas District** for storage of food under insanitary conditions that resulted in rodent or insect contamination.

Kroger Co., Irving, was fined \$1,500 and two of its officers—Richard D. Schill, Dallas Division vice president, and Anthony W. Cavalle, distribution center manager—were fined \$250 each for storage of food under insanitary conditions in which it became contaminated with rodent and insect filth. Judge William Taylor of the U.S. District Court for Northern Texas, Dallas, imposed the fines.

A. A. de la Torre & Sons, El Paso, and its four