

Vigo Forte tablets and vitamin B₁₂ and B₁ injection, 503(b) (4)—the articles were drugs subject to the provisions of 503(b) (1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without a prescription."

DISPOSITION: 7-20-61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS .

DRUGS FOR HUMAN USE*

6746. *Insta-Pep tablets*. (F.D.C. No. 43373. S. No. 82-806 P.)

QUANTITY: 17 cases of 36 50-tablet btls. and 10 cases of 72 25-tablet btls. at North Kansas City, Mo., in possession of Katz Drug Co.

SHIPPED: Between 6-24-59 and 8-26-59, from New York, N.Y., by Drug Research Corp.

LABEL IN PART: "Insta-Pep with Dynamol and 'Vitamin Feed' for prolonged Vitamin-Mineral Release A high potency therapeutic Vitamin-Iron formula * * * Each tablet contains: Thiamine Chloride (Vit. B₁) 15.0 mg. Riboflavin (Vit. B₂) 6.0 mg. Cobalamin Concentrate (Vit. B₁₂ Activity) 3.0 mg. Nicotinic Acid 30.0 mg. *Calcium Pantothenate 3.0 mg. *Choline Bitartrate 10.0 mg. Folic Acid 0.1 mg. *Inositol 20.0 mg. *dl-Methionine 20.0 mg. Iron (from Ferrous Sulfate) 30.0 mg. Ascorbic Acid (Vit. C) 90.0 mg. Pyridoxine Hydrochloride (Vit. B₆) 0.5 mg. Whole Liver Desiccate 25.0 mg. Calcium (from Dicalcium Phosphate) 30.0 mg. Phosphorus (from Dicalcium Phosphate) 20.0 mg. Sodium Acid Phosphate 100.0 mg. *Vitamin E (from d-alpha Tocopheryl Acid Succinate) 1.0 I.U. Iodine (from Potassium Iodide) 0.1 mg. Copper (from Cupric Sulfate) 1.25 mg. *Manganese (from Manganese Sulfate) 0.85 mg. *Cobalt (from Cobalt Sulfate) 0.04 mg. Potassium (from Potassium Sulfate) 0.65 mg. Magnesium (from Magnesium Sulfate) 0.50 mg. together with factors natural to liver content Caffeine Alkaloid Anhydrous 3.0 gr. Sole Distributors: Drug Research Corp. New York, N.Y."

ACCOMPANYING LABELING: Newspaper tear sheet, reading in part "Insta-Pep Stops Rapid Vitamin-Mineral Loss in Your Body! Fights Fatigue in 20 minutes! The Kansas City Star, Sunday, August 2, 1959."

RESULTS OF INVESTIGATION: The newspaper tear sheets were displayed with the article at various Katz Drug Stores in Kansas City, Mo.

LIBELED: 9-25-59, W. Dist. Mo.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was capable of providing instant pep; was the first new development in the vitamin field in over 20 years; stopped rapid vitamin-mineral loss in the body; fought fatigue in 20 minutes; stopped "vitamin let-down" even if tense, worried, or working under pressure; that feeling of fatigue as a result of tensions, worry and working under pressure is due to "vitamin let-down"; that chronic fatigue not aided by other vitamin preparations would be aided by *Insta-Pep tablets* to the extent that users would never feel tired any more; that *Insta-Pep tablets* contained a new, remarkable, amazing antifatigue factor; that "Dynamol" was a new "Vitamin-Mineral" discovery; that *Insta-Pep tablets* contained all necessary vitamins-minerals to build up the body; that the body throws off

*See also No. 6743.

most essential vitamins and minerals unless offered at the moment the body needs them; that vitamin preparations, other than *Insta-Pep tablets*, are passed out of the system in 3-4 hours; that *Insta-Pep tablets* released all the vitamins and minerals the body needs at the moment the body needs them; that tired feelings and rundown conditions are caused by vitamin deficiencies due to devitalized modern food, stress, conditions, or waste of vitamins by the body; that modern food is devitalized; that *Insta-Pep tablets* contained sufficient quantities of all the essential vitamins and minerals so that one tablet per day was an adequate cure and treatment for all vitamin and mineral deficiencies; that up to 80 percent of most vitamins and minerals in vitamin-mineral preparations, other than *Insta-Pep tablets*, are gone from the body in 4 hours; that the body may be vitamin-starved in less than 4 hours after taking vitamin preparations other than *Insta-Pep tablets*; that *Insta-Pep tablets* would materially increase physical strength of persons taking it; that *Insta-Pep tablets* would significantly increase mental alertness and ability to think more clearly; that *Insta-Pep tablets* would provide more vitamin-mineral benefits than higher potency formulas; that *Insta-Pep tablets* would relieve any normal fatigue in 20 minutes; that *Insta-Pep tablets* contained all vitamins and minerals necessary to build up the entire system; that the effect of the vitamins and minerals in *Insta-Pep tablets* was superior to all other vitamin-mineral preparations because it contained "Dynamol"; that the effect of the vitamins and minerals in *Insta-Pep tablets* was superior to all other vitamin-mineral preparations because it was contained in a sustained-action pill; that the use of "Dynamol" to relieve fatigue was new and one of the latest scientific developments; that use of *Insta-Pep tablets* would overcome the tired, rundown feeling of persons who take single dose vitamin preparations and still feel tired and rundown; that *Insta-Pep* was the first and only sustained release vitamin preparation; that *Insta-Pep tablets* gave 3 times the minimum daily adult requirements of all essential vitamins; that *Insta-Pep tablets* contained high-potency, therapeutic amounts of all vitamins and minerals essential to good health; that *Insta-Pep tablets* contained therapeutic amounts of all essential vitamins and minerals to be effective to adequately treat and cure diseases and symptoms due to any vitamin and mineral deficiency of long standing by taking one pill per day; that *Insta-Pep tablets* would help the body maintain essential levels of all necessary vitamins and minerals by taking one pill per day; that it was a multivitamin and mineral preparation containing all of the known vitamins and minerals essential to health; 502(a)—the labeling of the article contained statements which were misleading in that it failed to reveal that "Dynamol" is caffeine, and that each tablet contained the caffeine equivalent of two cups of coffee per day, and that relief of fatigue, if any, in twenty minutes was due to the action of the caffeine and not to the vitamin-mineral content; and that the article did not contain two essential vitamins, A and D, and did contain nutritionally insignificant amounts of the essential minerals, calcium and phosphorus; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of vitamin and mineral deficiencies.

DISPOSITION: On 11-25-59, Drug Research Corp. appeared as claimant and filed an answer denying that the article was misbranded. Thereafter, the claimant filed a motion for the transfer of the case for trial to the Eastern District of New York and, on 2-1-60, the court handed down the following decision:

MEMORANDUM AND ORDER

RIDGE, *District Judge*: "This is an action in libel, seeking forfeiture of certain drugs allegedly misbranded and shipped in interstate commerce in violation of the Federal Food, Drug & Cosmetic Act, (21 U.S.C.A. 301, etc.).

"Pursuant to the provisions of 21 U.S.C.A., Section 334(a), defendant has moved for an order transferring this case for trial to the United States District Court for the Eastern District of New York, at Brooklyn. The parties have been unable to stipulate for such removal because the Government urges that a transfer to the Eastern District of New York would be injudicious in light of the congestion of the court docket in that district. The Government suggests, instead, that the action be transferred to the District of New Jersey, a 'district of reasonable proximity to the claimant's principal place of business' where an early trial of this case may be had.

"Claimant's principal place of business is located in the Southern District of New York. The Court takes judicial notice of the fact that court in the Eastern District of New York is held at Brooklyn; court in the District of New Jersey is held at Newark; and that it is approximately an equal distance from both these places to Manhattan, in the City of New York, where court is held in the Southern District of New York. The 'Annual Report of the Director of the Administrative Office of the United States Courts,' dated September, 1959, reflects the comparative docket conditions and time interval involved in the disposition of civil cases filed and terminated in such jurisdiction during the fiscal year ending June 30, 1959.

"From an examination of Table C-5, C-5A, and C-6, appended to said report, it is revealed that the congestion of the docket in the Eastern District of New York is one of the heaviest in all the United States District Courts in the country; that the median time for the termination of business of cases filed in that district is one of the longest in the country; while the median time for disposition of business in the District of New Jersey is well below the average of all the other districts.

"Nothing in Section 334(a), *supra*, militates or prevents the transfer of this case to the District of New Jersey, a 'district in reasonable proximity to the claimant's principal place of business.' We can perceive no prejudice to claimant by such a transfer. Claimant will not be prejudiced in securing the attendance of any witnesses found in, or residents of, the Southern District of New York, nor will it be prejudiced by earlier trial of this case in the District of New Jersey, than if this case is transferred to the Eastern District of New York, which is a matter for consideration in the interest of justice.

"THEREFORE, IT IS ORDERED BY THE COURT that the Clerk transfer all papers on file in this case to the United States District Court for the District of New Jersey, at Newark, New Jersey, for further proceedings herein."

Following the removal of the case to the District of New Jersey the Government filed written interrogatories. The claimant filed answers to the interrogatories after which the Government filed a motion to compel more complete answers to the interrogatories. Such motion was granted by the court on 9-23-60. The claimant failed to file further answers to the interrogatories and, on 11-14-60, the court entered a default decree of condemnation and destruction.

6747. Various prescription drugs. (F.D.C. No. 46265. S. Nos. 97-714/15 R, 97-717 R.)

QUANTITY: Various quantities of prescription drugs and 1 25-tablet btl. labeled *Deronil*, at Corry, Pa., in possession of Corry Pharmacy.

SHIPPED: On unknown dates, from various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample" or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs originally intended for use as samples for physicians and others lawfully engaged