

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

541-600

DRUGS AND DEVICES

The cases reported herewith, commenced prior to June 30, 1940, were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Secretary of Agriculture; and those commenced on and after that date were similarly instituted upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, Acting Administrator, Federal Security Agency. Washington, D. C., October 10, 1942.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

Nos. 541 to 545 report actions based on interstate shipments of Nature's Minerals (in tablet and in powder form) which, with the exception of one shipment, contained fluorine in amounts which might have rendered them injurious to health; and with the exception of the shipment described in No. 543, bore false and misleading therapeutic claims in the labeling.

541. Misbranding of Nature's Minerals Compound. U. S. v. Perry B. Smith and Thornton B. Smith (Nature's Mineral Co.). Pleas of guilty. Fines, \$200. (F. D. C. No. 4178. Sample Nos. 26127-E, 26128-E, 26483-E, 26484-E, 35031-E, 35032-E.)

This product, in addition to being dangerous to health when used according to directions, because of its excessive fluorine content, also contained false and misleading claims in the labeling.

On October 27, 1941, the United States attorney for the Southern District of Indiana filed an information against Perry B. Smith and Thornton B. Smith, trading as Nature's Mineral Co., Indianapolis, Ind., alleging shipment from the State of Indiana into the States of Louisiana and Oregon, on or about August 26 and 29 and October 4, 1940, of quantities of Nature's Mineral Compound in powder and tablet form which was misbranded.

Analyses of samples of the article showed that it consisted essentially of compounds of calcium, magnesium, iron, and sodium, phosphates, carbonates, sulfates, chlorides, sulfur, and fluorine.

The article was alleged to be misbranded in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, since it contained a poisonous substance, fluorine. The shipment of August 29, 1940, was alleged to be misbranded further in that statements appearing on the carton and bottle labels and the design in an accompanying circular of a hotel surrounded by palm trees underneath which appeared the words "Instead of \$200.00 or \$300.00 a Month," followed by an arrow showing a home underneath which were the words "You spend only \$3.00 or 10¢ Per Day," and representations that the article could be used safely as an aid in supplying the minerals sometimes found deficient in the ordinary diet; that it would be efficacious in the treatment and alleviation of conditions for which a sojourn at a health resort is customarily prescribed; that the body normally requires the administration of alkaline substances to supplement those supplied by the usual and ordinary diet; that the effect of modern diet has been to modify the normal acid-alkali balance and, in cases of unbalance of the acid-alkali ratio, that the article would correct such unbalance; that it would restore health and prevent weakness; that the article was necessary to render the blood stream alkaline; that the ordinary diet is lacking in minerals and vitamins, which results in draining the system of its alkaline reserve; that it would correct the causes of flabby tissues and the effects of faulty elimination; that it would be efficacious to insure that the user would live to an advanced age without seeming old or losing his capacity to think or work; that it contained minerals which must be supplied specially; that it was needed for the proper functioning of important body processes; that the ordinary diet is deficient in minerals; that 99 percent of conditions of undernourishment are due to an acid condition and that it would enable every organ of the body to be nourished; that sickness, suffering, and shortness of life due to lack of minerals are general menaces; and that it would be efficacious to maintain or restore health, prevent loss of vitality, and remineralize the system, were false and misleading.

The remainder of the article was alleged to be misbranded further in that the statement appearing on the cartons and bottles, "Nature's Minerals * * * May be used as an aid in supplying in concrete form the minerals sometimes found deficient in the ordinary diet," were false and misleading since they represented that it could be used safely as an aid in supplying the minerals sometimes found deficient in the ordinary diet; whereas it could not be used safely for such purpose because of the presence of fluorine in deleterious

amounts.

The article also was alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2996.

On January 31, 1942, the defendants having entered pleas of guilty, the court imposed fines of \$150 against Perry B. Smith and \$50 against Thornton B. Smith.

542. Misbranding of Nature's Minerals Compound. U. S. v. 28 Vials of Nature's Minerals Compound Tablets and 24 Boxes of Nature's Minerals Compound (and 2 other seizures of similar products). Default decrees of condemnation and destruction. (F. D. C. Nos. 3121, 3122, 3379, 3380. Sample Nos. 26483-E, 26484-E, 35031-E, 35032-E.)

On October 4 and November 26, 1940, the United States attorneys for the Southern District of Mississippi and the District of Oregon filed libels against 28 vials of Nature's Minerals Compound Tablets and 24 boxes of Nature's Minerals Compound (in powder form) at Bay St. Louis, Miss., and 12 bottles of Nature's Minerals Compound Tablets and 21 cartons of Nature's Minerals Compound (in powder form) at Portland, Oreg, alleging that the articles had been shipped on or about August 29 and on or about October 4, 1940, by Nature's Minerals Co. from Indianapolis, Ind.; and charging that they were misbranded.

Analyses of samples of the articles showed that they consisted essentially of compounds of calcium, magnesium, iron, and sodium, phosphates, carbonates,

sulfates, chlorides, sulfur, and fluorine.

The articles were alleged to be misbranded (1) in that they would be dangerous to health when taken in accordance with the directions for use prescribed in the labeling; and (2) in that representations in the labeling [these representations are set forth in D. D. N. J. No. 541] were false and misleading since they would not be efficacious for such purposes.

They also were alleged to be adulterated and misbranded under the provisions

of the law applicable to foods, as reported in F. N. J. No. 2997.

On January 7 and February 25, 1941, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.