

ment should be stopped. Should a temperature of 100° F. persist for at least 24 hours, or in case of hemorrhage, the outside complicating factor causing this condition must at once be determined and treated accordingly. A temporary rise in temperature during paste treatment is no sign of danger. 5. In those rare cases where the first paste treatment fails to produce results, it may be repeated a week later provided there is no bleeding. 6. For cases up to and including six weeks of gestation the use of the modified strength of Leunbach' Paste (identified as package 'M') is suggested in an average dose of 15 Gms. 7. Spontaneous, and incomplete, as well as infected cases should be treated with a dose not exceeding 5 Gms. per month of gestation, up to a maximum of 25 Gms., injecting with but the slightest pressure. At term, Leunbach' Paste is contraindicated in the presence of placenta praevia and premature separation of placenta"; and (leaflet in both complete outfit and refill tube of lot seized at Los Angeles) "In those rare cases where the first paste treatment fails to produce results, it may be repeated a week later provided there is no bleeding. * * * For cases up to and including six weeks of gestation the use of the modified strength of Leunbach' Paste is suggested in an average dose of 15 Gms."

On October 7, 1940, no claimant having appeared for the lot seized at Atlanta, Ga., judgment of condemnation was entered and the product was ordered destroyed. On October 10, 1940, the decree was set aside, but on October 18, 1940, an order was entered reinstating the original judgment of condemnation and destruction.

Merz & Co. Chemical Works, Inc., appeared as claimant in the remaining seizures and filed answers denying the allegations of the libels. On March 24, 1941, the claimant filed a petition in the District Court for the District of Columbia praying removal of the case in that district and all other pending cases to the Eastern District of Pennsylvania for consolidation and trial. On March 25, 1941, an order was entered in the District Court for the District of Columbia in accordance with said prayer and the clerks of the various district courts were ordered to transmit to the Eastern District of Pennsylvania all records and papers in the proceedings pending in their respective jurisdictions.

On December 9, 1941, the answers filed by the claimant having been withdrawn by the receiver of the claimant corporation, which had filed a voluntary petition in bankruptcy, judgment of condemnation was entered and the products were ordered delivered to the Food and Drug Administration for its official use.

608. Misbranding of Leunbach' Paste. U. S. v. 1 Leunbach' Paste, Complete Outfit; and 7 Packages of Leunbach' Paste Refill Tube. Default decree of condemnation and destruction. (F. D. C. No. 7340. Sample No. 91220-E.)

On April 30, 1942, the United States attorney for the Northern District of Illinois filed a libel against the above-named drugs at Chicago, Ill., alleging that the articles had been shipped in interstate commerce on or about January 25, 1942, by the Doctors Pharmacy from Milwaukee, Wis.; and charging that they were misbranded. The articles were labeled in part: "Leunbach' Paste Complete Outfit"; or "Leunbach' Paste Refill Tube * * * Made in U. S. A. By Merz & Company Chemical Works, Inc., Newark, New Jersey."

The articles were alleged to be misbranded in that they were dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling. (The labeling accompanying the articles consisted of the circular and leaflet quoted in full in D. D. N. J. No. 607.)

On June 10, 1942, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

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

609. Adulteration and misbranding of Virgitalis, Rua-Balm, and Theobarb. U. S. v. Van Pelt & Brown, Inc. Plea of nolo contendere to first and second counts. Plea of guilty to remaining four counts. Total fines, \$300. (F. D. C. No. 4170. Sample Nos. 50070-E, 50095-E, 50129-E, 50130-E.)

The Virgitalis possessed a potency of approximately one-third of that declared. The Rua-Balm contained less alcohol than the amount declared and its labeling failed to bear such adequate warnings as are necessary for the protection of users. The Theobarb Tablets contained less phenobarbital than the amount declared.

On September 19, 1941, the United States attorney for the Eastern District of Virginia filed an information against Van Pelt & Brown, Inc., Richmond, Va., alleging shipment on or about September 12 and 21, 1940, and January 9, 1941,

from the State of Virginia into the District of Columbia of quantities of the above-named articles which were adulterated and misbranded.

The Virgitalis was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since each tablet purported and was represented to possess an activity equivalent to that possessed by $1\frac{1}{2}$ grains of whole digitalis leaf; whereas each tablet possessed an activity equivalent to not more than $\frac{1}{2}$ grain of whole digitalis leaf. It was alleged to be misbranded in that the statement "Each Tablet Assays * * * $1\frac{1}{2}$ grains Standardized Whole Digitalis Leaf (Physiologically Standardized)," appearing on the bottle label, was false and misleading.

The Rua-Balm was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since it was represented to contain 25 percent of alcohol, whereas it contained not more than 14 percent by volume of alcohol. It was alleged to be misbranded (1) in that the statement "Alcohol 25%," appearing on the carton and bottle label, was false and misleading; (2) in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient; and (3) in that its labeling did not bear adequate warnings against unsafe methods or duration of administration in such manner and form as are necessary for the protection of users, since it consisted chiefly of methyl salicylate and might cause excessive irritation of the skin, particularly if applied with rubbing, and should not be permitted to get into the eyes or mucous membranes, and its labeling did not bear the warning that it might cause excessive irritation of the skin, particularly if applied with rubbing, and that the user should avoid getting it into the eyes or mucous membranes.

The Theobarb was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess since each tablet was represented to contain $\frac{1}{4}$ grain of phenobarbital, whereas each tablet contained not more than 0.056 grain of phenobarbital. It was alleged to be misbranded in that the statement "Each Tablet Contains Phenobarbital $\frac{1}{4}$ Gr.," appearing on the bottle label, was false and misleading.

On October 16, 1941, pleas of nolo contendere as to counts 1 and 2 of the information and guilty as to counts 3, 4, 5, and 6 were entered on behalf of the defendant and the court imposed fines totaling \$300.

610. Misbranding of Atop Nerve Tonic. U. S. v. 8 Dozen Bottles of Atop. Default decree of condemnation and destruction. (F. D. C. No. 6217. Sample No. 74150-E.)

In addition to failure to bear adequate warning statements, the labeling of this product bore false and misleading therapeutic claims.

On November 15, 1941, the United States attorney for the Southern District of New York filed a libel against 8 dozen bottles of Atop Nerve Tonic at New York, N. Y., alleging that the article had been shipped on or about September 15 and October 20, 1941, by the W. J. Gilmore Drug Co. from Pittsburgh, Pa.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of chloral hydrate (12 grains per fluid ounce) and sodium bromide (29 grains per fluid ounce).

The article was alleged to be misbranded: (1) In that the labeling contained (a) no warning that it should not be taken by persons suffering from kidney diseases; (b) no warning that not more than the recommended dose should be taken; and (c) no warning that frequent or continued use might lead to mental derangement, skin eruptions, or other harmful effects. (2) In that representations in the labeling that it was an appropriate treatment for nervous exhaustion and that it relieved such symptoms as irritability, sleeplessness, headache, dyspepsia, eye fatigue, etc.; that it would overcome fear; that it would be an efficacious treatment for the delicate mental and emotional disorders of children; that it would prevent functional disturbances of the gastro-intestinal tract, cardiac system, and pelvic organs; that it would restore the normal impulses to the gastro-intestinal tract and relieve auto-intoxication; that it would help correct disorders of the endocrine glands; that it was an appropriate treatment for the effects of alcoholic indulgence; that it was conducive to quick recovery from surgical shock; that it was invaluable in anginoid cases and exceedingly helpful in other cardiac cases; and that it was of value in convalescence by increasing the appetite and assisting in regaining vitality, were false and misleading since it would not be efficacious for such purposes.

On December 3, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.