

of indigestion, dyspepsia, symptoms of indigestion, and other ailments due to imperfect or retarded functioning of the digestive organs, and that the article could be taken with perfect safety, were false and misleading since the article was not an adequate treatment for the conditions, ailments, and symptoms mentioned; and it could not be taken with perfect safety inasmuch as it contained a material proportion of sodium bromide.

The article was alleged to be further misbranded (1) in that its labels did not bear adequate directions for use since the directions appearing thereon, "Directions * * * Take a large tablespoonful after meals three times a day or whenever symptoms of indigestion occur. * * * Dose should be half a wineglassful followed by another dose in a half hour if necessary. The Remedy may be taken with perfect safety as often as necessary," provided for an excessive amount of sodium bromide and placed no limitation on the number of doses to be taken daily; (2) in that its labeling failed to bear any warnings that frequent or continued use of the article might lead to mental derangement, skin eruptions, or other serious effects, and that the article should not be taken by those suffering from kidney disease; and (3) in that it was dangerous to health when used in the dosage, or with the frequency prescribed, recommended, or suggested in the labeling, "Dose should be half a wineglassful followed by another dose in a half hour if necessary. The remedy may be taken with perfect safety as often as necessary."

The article, with the exception of that in the Newark lot, was alleged to be further misbranded in that the statement of the quantity or proportion of sodium bromide contained in the article did not appear on its label in such terms as to render it likely to be understood by the ordinary individual, since the statement on the label read "Sodium Bromide U. S. P. 3½%," whereas, in order to be understood by the ordinary individual, the sodium bromide contained in the article should have been declared in terms of grains per tablespoonful.

Between March 7 and September 6, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

PRODUCTS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

1203. Misbranding of Dimels. U. S. v. 68 Bottles and 1 Bottle of Capsules Dimels. Decree of condemnation and destruction. (F. D. C. No. 9914. Sample No. 3345-F.)

On or about May 12, 1943, the United States attorney for the Western District of Missouri filed a libel against 68 100-capsule bottles and 1 500-capsule bottle of the above-named product at Kansas City, Mo., alleging that the article had been shipped on or about March 11, 1943, from McKeesport, Pa., by Jones-Hague, Inc.; and charging that it was misbranded.

Examination disclosed that each capsule contained approximately 5 grains of a mixture of dried, powdered animal material and kaolin (China clay). The animal material was apparently of a glandular nature such as pancreas. It contained a small proportion of insulin and a starch-splitting enzyme equivalent to ½ percent pancreatin.

The article was alleged to be misbranded (1) in that it was a drug composed partly of insulin that was not from a batch for which a certificate or release had been issued pursuant to the law; (2) in that the statement on the label, "Each capsule contains Hormone Complexes as found in Isles Langerhans * * * Dosage—One capsule three times daily," was misleading in the absence of a statement of the material fact that, when consumed in accordance with the directions on the label, the article would not produce the well-known effects of the hormones found in the islands of Langerhans; and (3) in that the statements on the label, "To be taken only upon advice of physician. Its use otherwise may be dangerous. To be used only in uncomplicated and incipient Diabetes," were false and misleading since the article, if taken otherwise than upon advice of a physician, would not be dangerous, and it would be useless in the treatment of diabetes.

On January 11, 1944, Jones-Hague, Inc., having previously filed an answer denying the allegations of the libel and a brief in support of such answer, but having failed to make any further appearance in the proceedings, judgment of condemnation was entered and the product was ordered destroyed.