United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FOOD AND DRUGS ACT

[Given pursuant to section 4 of the food and drugs act]

18726–18750

[Approved by the Secretary of Agriculture, Washington, D. C., April 21, 1932]

18726. Adulteration and misbranding of tincture aconite. U. S. v. Eight 4-Ounce Bottles, et al., of Tincture Aconite. Default decrees of condemnation, forfeiture, and destruction. (F. & D. No. 26417. I. S. Nos. 5685, 5687. S. No. 4735.)

Samples of tincture aconite, labeled as conforming to the requirements of the United States Pharmacopoeia, were found to fall below the pharmacopoeial requirements. The article was contained in 4-ounce and 1-pint bottles, the samples of the former being found to possess about one-fourth the potency and the latter about three-eighths the potency of that required by the pharmacopoeia.

On May 27, 1931, the United States attorney for the Western District of New York, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid libels praying seizure and condemnation of eight 4-ounce bottles and five 1-pint bottles of the said tincture aconite, remaining in the original unbroken packages at Buffalo, N. Y., consigned by Sharp & Dohme, Philadelphia, Pa., alleging that the article had been shipped from Philadelphia, Pa., in part on February 24, 1931, and in part on May 2, 1931, and had been transported from the State of Pennsylvania into the State of New York, and charging adulteration and misbranding in violation of the food and drugs act. The article was labeled in part: "Tincture Aconite U. S. P. X. Standard."

It was alleged in the libels that the article was adulterated in that it was sold under a name recognized in the United States Pharmacopoeia, and differed from the standard of strength as determined by the tests laid down in the said pharmacopoeia official at the time of investigation, and its own standard of strength was not stated on the container. Adulteration was alleged for the further reason that the strength of the said article fell below the professed standard or quality under which it was sold, namely, "Tincture Aconite U. S. P. X. Standard."

Misbranding was alleged for the reason that the statements on the label, "Tincture Aconite U. S. P. X. Standard (Tinctura Aconiti) * * * Biologically standardized," were false and misleading.

On August 24, 1931, no claimant having appeared for the property, judgments of condemnation and forfeiture were entered, and it was ordered by the court that the product be destroyed by the United States marshal.

ARTHUR M. HYDE, *Secretary of Agriculture.*

18727. Misbranding of Spasmoline. U. S. v. 21 Bottles of Spasmoline. Default decree of condemnation, forfeiture, and destruction. (F. & D. No. 26353. I. S. No. 26347. S. No. 4675.)

The labeling of the drug product Spasmoline bore statements representing that the article possessed curative and therapeutic properties in certain children's ailments, and that it was perfectly safe and would not disorder the baby's stomach. Examination showed that it would not produce the curative and therapeutic effects claimed, that it was not perfectly safe, and might disorder the baby's stomach.

On May 15, 1931, the United States attorney for the Southern District of Indiana, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid a libel praying seizure and condemnation of 21 bottles of Spasmoline, remaining in the original unbroken packages at Indianapolis, Ind., alleging that the article had been shipped by the Spasmoline Co., McComb, Ohio, on or about September 12, 1930, and had been transported from the State of Ohio into the State of Indiana, and charging misbranding in violation of the food and drugs act as amended.

Analysis of a sample of Spasmoline by this department showed that it consisted essentially of castor oil (28 per cent by volume), extracts of plant drugs including ipecac, alcohol, sugar, and water.

It was alleged in the libel that the article was misbranded in that the statements in the circular, "It is perfectly safe at all times," and "In no case will it disorder the baby's stomach," were false and misleading. Misbranding was alleged for the further reason that the following statements appearing in the labeling, regarding the curative or therapeutic effects of the article, were false and fraudulent, since the said article contained no ingredient or combination of ingredients capable of producing the effects claimed: (Bottle label) "Spasmoline for the Relief of Coughs, Whooping Cough, Spasmodic Croup, * * * Directions. * * * If the child is not completely relieved in fifteen minutes, repeat the dose. For Cough, Whooping Cough * * * repeating in two or three hours, as the case demands. Spasmoline * * * Spasmoline Co.;" (carton) "Spasmoline * * * Instant Relief Acknowledged To Be The Best Remedy Ever Produced For Croup, Cough, Whooping Cough and all Affections of the Throat & Lungs * * * The Spasmoline Co. * * * Directions * * * in some obstinate cases it is necessary to repeat the dose * * * For croupy, wheezing, coughing children, * * * Given in the evening will prevent croup in the night. As a Child's Cough Medicine, Spasmoline Has No Equal. In cases of violent cough and whooping cough, use as the case may require. When a child is relieved of the croup, * * * Spasmoline will relieve Cold and prevent Pneumonia * * * Spasmoline * * * possessing great curative properties for all affections of the throat and lungs. * * * The rational treatment for Croup consists in administering a remedy, that will restore the child to a normal condition without debilitating the system by the use of strong emetics. Spasmoline is a reliable agent for this purpose. * * * it does not dispose the bowels to subsequent costiveness;" (small circular) "Spasmoline An effective remedy for Croup, Coughs, Whooping Cough, Etc.;" (large circular) "One Dose Relieves Croup * * * Spasmoline * * * The rational treatment for Croup consists in administering a remedy that will restore the Child to a normal condition without debilitating the system by the use of strong emetics. Spasmoline is a reliable agent for this purpose. * * * Spasmoline * * * possessing great curative properties for affections of the Throat. * * * Croup comes in the night and strikes its deadly blow before medical aid can be secured. Armed with a bottle of Spasmoline, you can drive this deadly enemy from your home and save your precious Child's life. For Cough, Whooping Cough, * * * Spasmoline has no superior."

On September 5, 1931, no claimant having appeared for the property, judgment of condemnation and forfeiture was entered, and it was ordered by the court that the product be destroyed by the United States marshal.

ARTHUR M. HYDE, *Secretary of Agriculture.*

18728. Misbranding of Nau's Dyspeptic Relief. U. S. v. 2 Dozen Packages of Nau's Dyspeptic Relief. Default decree of condemnation, forfeiture, and destruction. (F. & D. No. 26256. I. S. No. 22068. S. No. 4575.)

Examination of a drug product, known as Nau's Dyspeptic Relief, showed that the article was a combination treatment consisting of a liquid and tablets, and that the bottle label, the outer carton, and the carton containing the tablets bore statements representing that the article possessed curative and therapeutic properties which it did not possess.

On April 20, 1931, the United States attorney for the Northern District of California, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid a libel, and on May 27, 1931, an amended libel, praying seizure and condemnation of two dozen packages of the said Nau's Dyspeptic Relief, remaining in the original unbroken packages at San Francisco, Calif., alleging that the article had been