

**24030. Adulteration and misbranding of elixir terpin hydrate and codeine. U. S. v. Five 1-Pint Bottles, et al., of Elixir Terpin Hydrate and Codeine. Tried to the court. Judgment for the Government. Decree of condemnation, forfeiture, and destruction. (F. & D. nos. 27618, 27675. S. no. 5649. I. S. nos. 38724, 38736, 38737, 42759, 42760.)**

These cases involved shipments of a product, sold under a name recognized in the National Formulary, which differed from the standard laid down in that authority, since it contained no codeine alkaloid, one of the ingredients required by the National Formulary for elixir terpin hydrate and codeine, but did contain codeine sulphate, which is not found in the official article, and which is approximately 80 percent as potent physiologically, as codeine alkaloid. The article contained no syrup, an ingredient required by the formulary. The label declared the presence of codeine sulphate, but failed to state that codeine sulphate is a derivative of morphine or opium.

On January 4 and 20, 1932, the United States attorney for the Southern District of New York, acting upon reports by the Secretary of Agriculture, filed in the district court libels praying seizure and condemnation of 9 pint bottles and 37 gallon bottles of elixir terpin hydrate and codeine at New York, N. Y. On March 24 and April 6, 1932, respectively, amended libels were filed. It was alleged in the libels that the article had been shipped in interstate commerce, on various dates in October, November, and December, 1931, by the S. E. Massengill Co., from Bristol, Tenn., and that it was adulterated and misbranded in violation of the Food and Drugs Act.

The article was alleged to be adulterated in that it was sold under a name recognized in the National Formulary, and differed from the standard of strength, quality, and purity as determined by the test laid down in the said formulary official at the time of investigation. Adulteration was further alleged in that the strength and purity of the article fell below the professed standard or quality under which it was sold, namely, "Each fluid ounce represents codeine sulphate 1 gr. terpin hydrate 8 grs."

The article was alleged to be misbranded in that the statement, "Each fluid ounce represents codeine sulphate one gr. terpin hydrate 8 grs.", was false and misleading; and in that the packages failed to bear a statement on the label of the quantity or proportion of codeine sulphate contained in the article, since the statement was incorrect and failed to carry the information that codeine sulphate is a derivative of morphine or opium.

Samuel E. Massengill, trading as the S. E. Massengill Co., New York, N. Y., appeared as claimant and filed answers denying the material allegations of the libels. On October 1 and 2, 1934, the cases having been consolidated and a jury having been waived, the cases were tried to the court. On November 8, 1934, the court handed down the following opinion sustaining the charges that the article was adulterated in that it failed to conform to the requirements of the formulary, and was misbranded since it failed to declare on the label that codeine sulphate is a derivative of morphine or opium, and overruling the adulteration and misbranding charges based on the alleged failure of the article to correspond with the standard declared on the label (Patterson, *district judge*):

"The Food and Drugs Act provides that any food or drug adulterated or misbranded as defined in the act and shipped in interstate commerce shall be liable to seizure and forfeiture by proceedings analogous to proceedings in admiralty. By the act, a drug is to be deemed adulterated if it is sold under a name recognized in the United States Pharmacopoeia or National Formulary and if it differs from the standard of strength, quality, or purity therein laid down; so also if its strength or purity falls below the standard under which it is sold. Section 7; 21 U. S. C. A., section 8. A drug is to be deemed misbranded if the label on it is false and misleading; and in the case of a drug containing morphine, opium, or other specified substances or any derivative of them, it shall be deemed misbranded if the package fails to state the quantity or proportion of such substance or derivative. Section 8; 21 U. S. C. A., sections 9 and 10. There are other sorts of misbranding defined in the act, of no immediate importance.

"The United States seized on two occasions a number of bottles of a liquid drug owned by one Massengill and labeled 'Elixir Terpin Hydrate and Codeine (Special). Alcohol 30%. Each fluid ounce represents: Codeine Sulphate 1 gr., Terpin Hydrate 8 grs., Glycerin q. s.' Two libels for forfeiture were filed, one for each seizure. The charge against the articles was that they were adulterated and also misbranded. Massengill appeared as claimant in each suit. The suits were tried together, and a jury waived.

"1. In the National Formulary there is a product listed as elixir of terpin hydrate and codeine. The ingredients and quantities specified for it differ materially from the ingredients and quantities set forth on the labels of the bottles seized and also from the actual contents of the bottles. The first question presented is whether the drug was adulterated because sold under a name recognized in the National Formulary but not in fact conforming to the standard required by it. The claimant's contention is that the word 'special' in the name on the label, 'Elixir Hydrate and Codeine (Special)', is an indication that the product is not the elixir of terpin hydrate and codeine defined in the formulary, and certain expert testimony in support of this contention was offered. But the question is not what the chemist or the druggist may understand by the addition of the word 'special' to the title. The Food and Drugs Act was passed as a protection to the uninformed, that they might be assured that an article purchased was what it purported to be. *United States v. Lexington Mill Co.*, 232 U. S. 399, 409; *United States v. Coca Cola Co.*, 241 U. S. 265, 276. Certainly the average consumer would not be put on guard that a compound called 'elixir terpin hydrate and codeine (special)' was not the elixir of terpin hydrate and codeine listed in the formulary. The word 'special' might well signify to him merely that the ingredients were especially pure or that the product was manufactured with special care. If a manufacturer wishes to use a National Formulary name for a nonconforming product, it is his duty to give the public unmistakable notice that in its composition there has been a departure from the formula given in the formulary.

"The Regulations for Enforcement of the Food and Drugs Act, adopted by the Department of Agriculture, have an appropriate provision. Regulation 7 (b) provides: 'A drug sold under a name, or a synonym, recognized in the United States Pharmacopoeia or the National Formulary which does not conform to the standard of strength, quality, or purity for the article as determined by the test laid down therein shall be labelled with a statement to the effect that the drug is not a United States Pharmacopoeia or National Formulary article \* \* \*'

"This regulation is interpretive and explanatory of the statute, not an attempted addition, and there is no doubt of its validity. See *United States v. Antikamnia Co.*, 231 U. S. 654. The mere word 'special' is not a statement that the product bearing a formulary name is not a formulary article. I am of opinion that the drug was adulterated in that it was sold by a name recognized in the National Formulary but varying from the standards there laid down.

"2. The second question is whether the drug was misbranded for not stating on the container that codeine sulphate is a derivative of opium or morphine. That codeine is a derivative of opium or morphine is undisputed. The presence of codeine sulphate was shown by the label, but it was not stated that codeine sulphate is a derivative of opium or morphine. The act, section 8, declares that a product containing morphine or opium or any derivative must bear a statement of the quantity or proportion of the substance or derivative. In the *Antikamnia* case, supra, the point was squarely raised whether it was a sufficient compliance merely to name the derivative or whether the manufacturer was required to go further and to state of what substance the derivative was. The court construed the statute as putting on the manufacturer the double duty. In the case of a drug containing acetphenetidin, a derivative of acetanilid, he was called upon to state on the package that the article contained acetphenetidin and that this was a derivative of acetanilid. The rule is applicable here. The packages under seizure did not bear any notice that codeine is a derivative of opium or morphine. They were therefore misbranded.

"3. The final question is whether there was adulteration or misbranding on the score that the contents of the bottles did not correspond with the declarations on the labels. The labels stated that each ounce contained 1 grain of codeine sulphate and 8 grains of terpin hydrate. There was testimony by Government chemists that on analyses there was more terpin hydrate than the quantity declared and less codeine sulphate. On the other hand, there was testimony that when compounded the products had precisely the quantities specified on the label, and there was testimony that the test for terpin hydrate is not a satisfactory one. The variations found by the Government chemists, taken as a whole, are not wide, and I am not prepared to say that they are beyond the zone of experimental error and tolerance in manufacture. The burden of proof is on the United States, and the proof does not establish adulteration or misbranding by reason of discrepancy between the quantities set forth on the labels and the actual contents of the bottles.

"There will be a decree of forfeiture for adulteration and misbranding. Findings and conclusions in conformity with this opinion may be submitted." On December 3, 1934, judgment of condemnation was entered and the product was ordered destroyed.

M. L. WILSON, *Acting Secretary of Agriculture.*

**24031. Adulteration and misbranding of Occo Mineral Compound for Sheep, Occo Mineral Compound for Hogs, and Occo Mineral Compound for Poultry. U. S. v. Oelwein Chemical Co. Tried to the court. Judgment of guilty on counts 1, 2, 3, and 4; not guilty on counts 5 and 6. Fine, \$200 and costs. (F. & D. no. 30225. I. S. nos. 41008, 41009, 41010.)**

The offense charged in this case was the adulteration and misbranding of stock and poultry compounds in which certain ingredients declared on the labels were present in smaller amounts than represented, or entirely absent. The products were represented to be "vitamized." However, tests of each product showed that 12 grams were not equal to 1 gram of good-grade dried yeast as a source of vitamin B. Tests of the stock and poultry compounds showed that 200 grams were not equal to 1 gram of good grade cod-liver oil as a source of vitamin D.

On May 29, 1934, the United States attorney for the Northern District of Iowa, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Oelwein Chemical Co., a corporation, Oelwein, Iowa, alleging shipment by said company, in violation of the Food and Drugs Act, on or about September 18, December 8, and December 12, 1931, from the State of Iowa into the State of Minnesota, of quantities of Occo Mineral Compound for Sheep, Occo Mineral Compound for Poultry, and Occo Mineral Compound for Hogs, which were misbranded. The articles were labeled in part: "Vitamized Occo Mineral Compound for Sheep [or "Poultry" or "Hogs"] \* \* \* Oelwein Chemical Company Oelwein, Iowa."

Analyses showed that the compound for sheep consisted of a mixture containing essentially salt (sodium chloride), Glauber's salt (sodium sulphate), lime, calcium carbonate, calcium phosphate, charcoal, sulphur, and copperas (iron sulphate); that the compound for poultry consisted of a mixture containing essentially salt (sodium chloride), Glauber's salt (sodium sulphate), lime, calcium carbonate, calcium phosphate, charcoal, sodium bicarbonate (baking soda), sulphur, copperas (iron sulphate), and a small amount of plant material; and that the compound for hogs consisted of a mixture containing essentially salt (sodium chloride), Glauber's salt (sodium sulphate), lime, calcium carbonate, calcium phosphate, charcoal, sulphur, copperas (iron sulphate), and sodium bicarbonate (baking soda).

The articles were alleged to be adulterated in that their strength and purity fell below the professed standard and quality under which they were sold, in the following respects: The sheep compound was represented to contain fenugreek, powdered African ginger, cod-liver oil fortified with vitamin D, potassium iodide, yeast, and not less than 0.477 percent of iodine, whereas it contained no fenugreek, no powdered African ginger, no cod-liver oil fortified with vitamin D, no potassium iodide, no yeast, and no iodine; the poultry compound was represented to contain powdered capsicum, powdered African ginger, cod-liver oil fortified with vitamin D, yeast, lime (CaO) not less than 31.25 percent, a trace of iodine, African ginger, and capsicum, whereas it contained no capsicum, no powdered capsicum, no powdered African ginger, no African ginger, no cod-liver oil fortified with vitamin D, no yeast, not more than 28.7 percent of lime (CaO) and no iodine; the hog compound was represented to contain wormseed, potassium iodide, ginger, molasses, columbo, yeast, cod-liver oil fortified with vitamin D and a trace of iodine; whereas the article was alleged to contain no wormseed, no potassium iodide, no ginger, no molasses, no columbo, no yeast, no cod-liver oil fortified with vitamin D, and no iodine.

Misbranding was alleged for the reason that the following statements, (sheep compound) "Ingredients Guaranteed \* \* \* Foenugreek \* \* \* Pwd. African Ginger \* \* \* Cod Liver Oil fortified with Vitamin D \* \* \* Potassium Iodide \* \* \* Yeast \* \* \* Guaranteed Analysis \* \* \* Iodine (1) not less than .0477%", (poultry compound) "Pwd. Capsicum \* \* \* Pwd. African Ginger \* \* \* Cod Liver Oil fortified with Vitamin D Yeast \* \* \* Guaranteed Analysis Lime (CaO) not less than 31.25% \* \* \* Iodine (1) not less than Trace \* \* \*", (hog compound) "Ingredients: \* \* \* American Worm Seed Potassium Iodide \* \* \* Ginger \* \* \* Molasses \* \* \* Columbo-Yeast \* \* \* Codliver Oil