

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]

29751-29800

[Approved by the Acting Secretary of Agriculture, Washington, D. C., January 24, 1939]

29751. Adulteration and misbranding of Elixir Sulfanilamide. U. S. v. Samuel Evans Massengill (The S. E. Massengill Co.). Demurrer to information. Overruled as to certain counts; sustained as to remaining counts. Plea of guilty. Fine, \$16,800. (F. & D. No. 40813. Sample Nos. 24540-C, 24541-C, 33799-C, 39097-C, 39593-C, 43872-C, 43873-C, 43876-C, 44259-C, 44261-C, 44262-C, 44360-C, 47326-C, 47328-C, 47453-C to 47459-C, inclusive, 47461-C to 47464-C, inclusive, 47466-C, 47467-C, 47470-C, 47477-C to 47482-C, inclusive, 48079-C, 48537-C, 49901-C, 49902-C, 49903-C, 50033-C, 53400-C, 53703-C, 53705-C, 54104-C, 56875-C, 57301-C, 57302-C, 57879-C, 57880-C, 57901-C, 57902-C, 59531-C, 59532-C, 59533-C, 61156-C, 61226-C, 61301-C.)

The labeling of this article was such as to create the impression that it consisted of sulfanilamide in a nonpoisonous solvent; whereas it consisted of sulfanilamide in a poisonous solution, i. e., diethylene glycol and water.

On June 10, 1938, the United States attorney for the Eastern District of Tennessee, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Samuel Evans Massengill, trading as the S. E. Massengill Co. at Bristol, Tenn., alleging shipment by said defendant in the period from on or about September 4, 1937, to on or about October 15, 1937, from the State of Tennessee into the States of California, Georgia, South Carolina, Virginia, New York, Mississippi, North Carolina, Florida, West Virginia, Michigan, Kentucky, Alabama, Maryland, and Indiana of quantities of Elixir Sulfanilamide which was adulterated and misbranded.

The article was alleged to be adulterated in that its purity fell below the professed standard or quality under which it was sold since it was represented to be sulfanilamide in a nonpoisonous solvent; whereas it was sulfanilamide in a poisonous solvent, diethylene glycol and water.

Misbranding was alleged in that the statement "Elixir Sulfanilamide," borne on the bottle label, was false and misleading in that the said statement represented that the article was sulfanilamide in a nonpoisonous solvent; whereas it was sulfanilamide in a poisonous solvent, diethylene glycol and water. Misbranding was alleged further in that the statement "Quality Pharmaceuticals," borne on the sticker attached to the stoppers of the bottles in most of the shipments, was false and misleading in that said statement represented that the article was of superior grade, i. e., that it was a mixture of substances intended to be used for the cure, mitigation, or prevention of disease and was suitable and appropriate for such purposes; whereas it was not of a superior grade and did not consist of a mixture of substances suitable and appropriate to be used for the cure, mitigation, or prevention of disease, in that it was a poisonous mixture.

The defendant filed a demurrer to all counts of the information, which was argued on September 26, 1938. On September 29, 1938, the court rendered a decision sustaining the demurrer on the counts charging misbranding because of the statement "Quality Pharmaceuticals," borne on the sticker, and overruling the demurrer on the remaining counts. In ruling on the demurrer to the remaining counts of the information the court said:

(Taylor, *District Judge*) "In this demurrer, I have given very careful consideration to the authorities cited by the parties, and have been very much interested in the nice distinctions that have been drawn, particularly as to the cases in which foods are involved, and cases in which medicines are involved, or drugs.

"For the purpose of the demurrer, I shall refer specifically only to the second count, which is typical of all of the counts, charging misbranding by the use of a label containing the words 'Elixir Sulfanilamide.'

"The attack upon this typical use charge is that the claim of the misleading and false character of the label, which lies in the implied representation that the sulfanilamide, that the Elixir Sulfanilamide, the medicinal property, is in a nonpoisonous solvent, is untenable.

"The information charges that the word 'elixir' denotes a nonpoisonous vehicle or solvent. The defendant contends that the information makes no such charge, and that the word has no such meaning actually, and that it has acquired no such secondary meaning, and that no such secondary meaning is alleged or charged.

"I have reached the conclusion that a fair construction of the language of the information is that the word 'elixir' used in connection with the word 'sulfanilamide' constitutes a representation that the contents of the package or bottle contained no ingredient which used as elixirs as used by the profession, and as directed by the manufacturer, would either counteract the effect of the active drug sulfanilamide, or kill or seriously injure the patient. If this construction clearly be correct, the charge clearly presents an issue of fact to be determined, and if determined in favor of the Government's contention, an offense against the act exists.

"I have very carefully considered the defendant's contention that such charged representation relates not to the character of the ingredient, but to the physiological effect of the ingredient; in other words, that it does not deal with the question of strength or purity, but rather comes within the class of cases of which the cancer case is typical, and is not, therefore, violative of the statute, which relates to drugs as distinguished from foods. I think the language employed by the Supreme Court of the United States in the case of *United States v. Johnson*, 211 U. S. 488, is authority for the conclusion I have reached, if I have placed the correct construction upon the allegations in the information. The Johnson case is the case just above referred to, as I recall it.

Entertaining this view as applicable to all of the counts, the demurrer will be generally overruled and the defendant required to plead to the merits.

On October 3, 1938, the defendant entered a plea of guilty to the counts on which the demurrer had been overruled and the court imposed a fine of \$150 on each of the counts, a total of \$16,800.

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

29752. Adulteration and misbranding of Elixir Sulfanilamide. U. S. v. Samuel Evans Massengill (S. E. Massengill Co.). Plea of guilty. Fine, \$9,300. (F. & D. No. 40830. Sample Nos. 21573-C, 48976-C, 49180-C, 49181-C, 58205-C, 58207-C, 58208-C, 58211-C, 58212-C, 58410-C to 58421-C, inclusive, 59825-C, 59826-C, 62979-C to 62983-C, inclusive, 64459-C, 64494-C.)

On June 3, 1938, the United States attorney for the Western District of Missouri, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Samuel Evans Massengill, trading as the S. E. Massengill Co. at Kansas City, Mo., alleging shipment by said defendant within the period from on or about September 14, 1937, to on or about October 8, 1937, from the State of Missouri into the States of Texas, Arkansas, Oklahoma, Wisconsin, and Illinois, of quantities of Elixir Sulfanilamide. The information further alleged the sale by said defendant under a guaranty that it conformed to the requirements of the Food and Drugs Act of quantities of the product, and its subsequent shipment during the same period from the State of Missouri into the State of Illinois. The adulteration and misbranding charges were identical with those contained in the information filed in the Eastern District of Tennessee against the same product reported in notice of judgment No. 29751.

On October 19, 1938, the defendant entered a plea of guilty to the counts charging adulteration and those charging misbranding based on the statement in the label, "Elixir Sulfanilamide." A fine of \$150 was imposed on each of the said counts, or a total of \$9,300. The remaining counts were dismissed.

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