

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

901-950

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*
Washington, D. C., August 10, 1944.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

901. Action to restrain interstate shipment of "Interferin," a misbranded drug. U. S. v. Don Curtis Keefer (Keefer Laboratories). Permanent injunction granted. (Inj. No. 33.)

On June 29, 1942, the United States attorney for the Northern District of Illinois filed a complaint against Don Curtis Keefer, trading as the Keefer Laboratories at Chicago, Ill., alleging that the defendant for several months past and more particularly on or about November 3 and November 27, 1941, had been and was introducing and delivering for introduction into interstate commerce, a drug labeled and designated "Interferin"; that the drug was compounded of potassium soap, sodium soap, potassium iodide, benzoic acid, fats and oils, alcohol, and water, and was so compounded and manufactured as to form a paste; that it was sold in a collapsible tube of 60 cc. capacity, bearing a label and packed in a cardboard carton together with implements to be employed in the injection of the paste; that enclosed in the cardboard carton and accompanying the article was a leaflet which contained certain statements in reference to the efficacy of the drug and as to the quantity, dosage, and administration thereof; that the statements appearing in the labeling represented, suggested, and engendered the impression in the mind of the reader that the drug was a safe and effective medicament for effecting abortion, whereas it was not such a safe and effective medicament, but was a drug which has dangerous effects on the human body; and that the article was further misbranded in that it was dangerous to health

¹ For omission of accurate statement of quantity of contents, see Nos. 908, 911, 914, 932, 934; omission of, or unsatisfactory, ingredients statements, Nos. 907, 908, 911, 926, 932, 935, 940, 942; inconspicuousness of required label information, Nos. 913, 923; deceptive packaging, Nos. 930, 938; no new-drug application effective, No. 910; presence of a habit-forming narcotic without warning statement, Nos. 904, 911, cosmetic, subject to the drug provisions of the Act, No. 942.

when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling.

The complaint alleged further that the defendant, unless restrained and enjoined, would continue to introduce and deliver the article for introduction into interstate commerce, misbranded in the manner aforesaid, and would similarly continue to evade and defeat the provisions of the law to the injury of the public; and prayed that the defendant, his agents, employees, and representatives, and all others acting by or under his direction or authority, and all persons, firms, companies, and corporations and their respective officers, servants, employees, and representatives in active concert or participation with the defendant, be perpetually enjoined and restrained from, in any manner of by any device, directly or indirectly, further introducing or delivering the article, or a similar article for introduction into interstate commerce, misbranded in the manner aforesaid, or similarly, and that, upon hearing, a preliminary injunction be granted restraining the defendant during the pendency of the action.

On July 3, 1942, the matter having come on before the court for hearing on the complaint and affidavits filed by the United States attorney, the court entered a preliminary injunction. On July 30, 1942, a permanent injunction was entered as prayed in the complaint.

902. Misbranding of ampuls of sodium salicylate and sodium iodide with colchicine, and adulteration and misbranding of thyroid and ovarian compound. U. S. v. Kenneth Gaylord Ziegler (Ziegler Pharmacal Co.). Plea of guilty. Fine, \$450. Payment of fine suspended. (F. D. C. No. 7740. Sample Nos. 40863-E, 42995-E.)

On November 23, 1942, the United States attorney for the Western District of New York filed an information against Kenneth Gaylord Ziegler, trading as Ziegler Pharmacal Company, Buffalo, N. Y., alleging shipment on or about August 19 and September 16, 1941, of the above-named products from the State of New York into the State of Pennsylvania.

Analysis of a sample of the ampuls of sodium salicylate and sodium iodide with colchicine showed that the volume of the contents varied from 18.8 to 20.5 cc. The average was 19.47 cc.

The article was alleged to be misbranded in that the statement, "20 c. c. Plus," borne on the label was false and misleading since it represented that the ampuls contained 20 cc. of the article, plus an amount sufficient to insure a full dosage of 20 cc. when administered in the manner that is customary and usual, whereas a large proportion of the ampuls contained less than 20 cc. of said drug, and all of the ampuls contained less than an amount sufficient to insure a full dosage of 20 cc. when administered in a manner that is customary and usual.

Examination of a sample of the thyroid and ovarian compound showed the tablets to contain 0.015 grain ($\frac{1}{67}$ grain) of arsenic trioxide each.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, $\frac{1}{80}$ grain of arsenic trioxide.

It was alleged to be misbranded (1) in that the statement on the label, "Arsenic Trioxide $\frac{1}{80}$ gr.," was false and misleading since the tablets were found to contain not less than $\frac{1}{67}$ grain of arsenic trioxide; (2) in that its name, "Thyroid and Ovarian (Compound)," was false and misleading since it suggested that the article was composed solely of thyroid and ovarian glandular substances, whereas, in addition, it contained strychnine sulfate and arsenic trioxide; (3) in that the statement, "Ovarian * * * Dose: One or two tablets three times a day," borne on the label was false and misleading since it suggested that in the dosages recommended the drug would supply the user with a significant amount of the active principles of ovarian glands, whereas it contained an inconsequential amount of the active principles of ovarian glands; (4) in that it contained strychnine and, because of the presence of strychnine, not more than the dosage recommended should be taken, its frequent or continued use should be avoided, and its use by children and elderly persons might be especially dangerous; (5) in that it contained arsenic and its labeling did not bear adequate warning that continued or prolonged use of a preparation containing arsenic might result in serious injury; and (6) in that it contained thyroid and would be dangerous to health when used in the dosage or with the frequency of duration prescribed, recommended, or suggested in the labeling.

On November 23, 1942, the defendant entered a plea of guilty to the 3 counts in the information. He was sentenced to pay a fine of \$150 on each count, but payment of the fine was suspended.