

4131. Adulteration and misbranding of first aid kits. U. S. v. 414 First Aid Kits * * *. (F. D. C. No. 34465. Sample No. 69257-L.)

LIBEL FILED: January 6, 1953, District of Colorado.

ALLEGED SHIPMENT: On or about November 13, 1952, by the E. D. Bullard Co., from San Francisco, Calif.

PRODUCT: 414 *first aid kits*, consisting of a metal case with a hinged lid and containing first aid supplies at Denver, Colo.

The kits contained, among other items, an unlabeled glass ampul covered with a mesh cloth and a tube of ointment. Analysis of the contents of the glass ampul showed that it contained ammonia, a red color, and aromatic substances. Analysis of the ointment showed that it contained less than the declared 1.5 percent of carbolic acid.

LABEL, IN PART: (Tube) "Carbolated Petrolatum (Carbolic Acid 1.5%) Kip, Inc. Los Angeles 21, Calif. 1/8-oz. Avoir."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the component of the article labeled, in part, "Carbolated Petrolatum" differed from that which it was represented to possess since it contained less than 1.5 percent of carbolic acid.

Misbranding, Section 502 (b) (1) and (2), the article contained in the unlabeled glass ampul failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (e) (2), the article in the ampul was fabricated from two or more ingredients, and it failed to bear a label containing the common or usual name of each active ingredient.

DISPOSITION: May 21, 1953. Default decree of condemnation. The court ordered that the unlabeled glass ampuls and the tubes of ointment be removed from the first aid kits and destroyed, and that after such removal and destruction, the first aid kits be given to a Federal institution for its use and not for sale.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4132. Action for declaratory judgment or injunction. Research Laboratories, Inc., v. Robert E. Hannegan, et al. Complaint dismissed.

COMPLAINT FILED: On or about August 8, 1947, Research Laboratories, Inc., Portland, Oreg., plaintiff, filed a complaint in the United States District Court for the District of Columbia, against Robert E. Hannegan (Post Office Department), Watson B. Miller (Federal Security Agency), and Paul B. Dunbar (Food and Drug Administration).

NATURE OF CHARGE: It was alleged in the complaint, with respect to matters arising under the Federal Food, Drug, and Cosmetic Act, (1) that the Food and Drug Administration had initiated against a drug known as *Nue-Ovo* several libel for condemnation proceedings in the district courts during the period between 1929 and the time of filing the complaint; (2) that at least three "hearings" under Section 305 of the Act had been conducted by the Food and Drug Administration's representatives, which "hearings," it was alleged, were a means of further harassing the plaintiff and those associated with it; (3) that the Federal Trade Commission, between 1930 and 1935, conducted extensive investigation of the plaintiff's conduct, but no regulatory action

*See also Nos. 4127-4129.

was taken under the Federal Trade Commission Act; (4) that plaintiff's counsel, after the entry of a decree of condemnation in 1946 and during the pendency of an appeal therefrom, discovered an irregularity in the labeling of the drug, and thereupon the plaintiff revised the said labeling and literature; (5) that the plaintiff advised Defendant Dunbar, on April 8, 1947, of the revisions made and sought his advice and comment, but that defendant refused to discuss the said revisions with plaintiff's attorneys, giving as his reason that the Food and Drug Administration could not enter into such discussions so long as litigation respecting the product was in progress; and (6) that, on August 4, 1947, the Food and Drug authorities made a further seizure of plaintiff's product, which was stored in a warehouse and was not for sale, though technically misbranded.

PRAYER FOR RELIEF: That the defendants be ordered to come forward and state any and all objections they might have to plaintiff's product, its labeling, or literature, and that the court determine the merits of such objections that might be made; and that the defendants be restrained from taking further administrative or enforcement action under the Federal Food, Drug, and Cosmetic Act, or, in the alternative, that a judicial declaration be issued as to plaintiff's rights with respect to the distribution of its product.

DISPOSITION: A motion for dismissal of the complaint was filed on behalf of the Government, and, on December 18, 1947, the court handed down the following opinion in favor of the motion:

MCGUIRE, Associate Justice: "There is no justiciable controversy here. *Aetna Life Insurance Company v. Haworth et al.*, 300 U. S. 227-240, 241. *Helco v. McNutt*, 137 F. 2d 681, 683, 687.

"*Currin v. Wallace* (306 U. S. 1) can be distinguished. There, there was an actual controversy of a real and substantial character going to the constitutionality of the Tobacco Inspection Act (Aug. 13, 1935) as the Circuit Court held, which view the Supreme Court adopted.

"Here, however, no such definitiveness exists. The declaratory judgment is not a substitute for a new trial or for an appeal from a former judgment deciding identical issues or issues which the court believes were necessarily passed upon. Borchard: *Declaratory Judgments*, 355. Nor can the Federal Security Agency under guise of this remedy be compelled to give an advisory opinion in futuro or to place its nihil obstat on some contemplated labeling of the plaintiff's product—that is neither its established purpose or function.

"Again, infraction of Title 21, § 331 USCA is a criminal act (§ 333) and what the plaintiff here is actually seeking is an advisory opinion *in limine* as to the criminality or lack of criminality of its prospective sales activities.

"Motion to dismiss granted. Counsel will prepare proper order."

Pursuant to the above opinion, an order was entered on January 8, 1948, dismissing the complaint. Research Laboratories, Inc., as plaintiff, thereafter filed a motion to vacate the order of dismissal; and, on October 26, 1948, after consideration of the arguments of counsel, the court denied the motion.

4133. Misbranding of inorganic nutrient tablets, soya lecithin, dicalcium phosphate tablets, and calcium phytate tablets. U. S. v. Inorganic Bioelements, Inc., and John F. Wischhusen. Pleas of nolo contendere. Fine of \$300 against each defendant. (F. D. C. No. 33751. Sample Nos. 7852-L, 7853-L, 18773-L, 18775-L.)

INFORMATION FILED: January 13, 1953, Northern District of Ohio, against Inorganic Bioelements, Inc., Cleveland, Ohio, and John F. Wischhusen, a director of the corporation.