the *Pile-Dume* consisted essentially of the chlorides and carbonates of sodium, potassium, calcium, and magnesium in a fatty base containing some water.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading. The statements represented and suggested that the *Mel-O-Eze* would be effective in the treatment of athlete's foot and eczema; that the *Mount Clemens Mineral Salts* would be effective in the treatment of rheumatism, nervousness, neuritis, and arthritis, and for the relief of that tired, weary, run-down feeling and body fatigue; that the *Mount Clemens Cleme-Tone Concentrated Mineral Water* would be effective in the treatment of gastric hyperacidity and ulcerated stomach; and that the *Pile-Dume* would be effective in the treatment of bleeding and protruding piles. The articles would not be effective for such conditions.

Further misbranding, Section 502 (f) (2), the labeling of the *Pile-Dume* failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, since its labeling failed to warn that bleeding may be an indication of cancer.

DISPOSITION: January 13, 1949. The Mount Clemens Mineral Water Co., Mount Clemens, Mich., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

2555. Misbranding of Tox Eliminator devices. U. S. v. 2 * * *. Tried to the court. Verdict for the Government. Decree of condemnation and destruction. (F. D. C. No. 24752. Sample Nos. 68180–H, 68181–H.)

LIBEL FILED: May 10, 1948, Eastern District of Oklahoma; amended libel filed July 9, 1948.

ALLEGED SHIPMENT: On or about December 2 and 26, 1946, by the Tox Eliminator Co., from Glendale, Calif., and Louisville, Ky.

PRODUCT: 2 devices known as *Tox Eliminator* at Poteau, Okla. The device was an apparatus for flushing the colon.

NATURE OF CHARGE: Misbranding Section 502 (a), certain statements in the accompanying labeling of the device, consisting of circular letters dated January 1, 1947, addressed to "Dear friend" and leaflets entitled "The Modern, Scientific Drugless Way to Health" and "The Magic Power of Water," were false and misleading. These statements represented and suggested that the device was effective in helping to purify the blood stream in performing its marvelous function of healing and correcting in all parts of the body; in treating intestinal toxemia, arthritis, rheumatism, neuritis, high and low blood pressure, toxic heart conditions, ulcers of stomach and bowels, colitis, chronic appendicitis, gall bladder and liver troubles, kidney and bladder troubles, asthma, migraine, toxic skin troubles, lumbago, excessive fatigue, foul breath, indigestion, irregular heart, menopause disturbances, muddy or pimply complexion, nervousness, pruritus, sinus trouble, run-down condition, shortness of breath, sleeplessness, ulcers of the colon, and disturbed bowel conditions; in giving necessary tone to the tissues; in cleansing the blood stream by assisting in eliminating the causes of blood pollution; in assisting in relieving sinus and antrum complications; helping to re-establish a normal peristalsis or natural muscular activity of the intestines; in helping improve the complexion by assisting in eliminating the causes of pollution of the blood stream; in helping to prevent hardening of the arteries by minimizing the

deposits of calcium and magnesium salts on arterial walls; in assisting in a more rapid recovery from a major surgical operation; in removing at their source disease-producing materials not properly discharged by the liver, colon, and kidneys, and as a result carried by the blood and lymph stream to every part of the body, tissues, joints, sinus, appendix, gall bladder and so on, thereby helping the body to stop further damage and helping nature rebuild the affected parts and restore them to normal; in removing causes of irritation and numerous infections; in treating acute and chronic disorders; in helping to determine the cause of a great many gastrointestinal disorders; and in treating female disorders, prostatic disorders, rectal diseases, sciatica, heart involvements, and many other pathological conditions too numerous to mention. The device was not effective for such purposes.

It was alleged also in the libel that if it should be determined that the leaflets and circular letters did not accompany the device, the device was misbranded under Section 502 (f) (1), in that its labeling failed to bear adequate directions for use since the labeling failed to state any diseases or conditions for which the device was intended to be used; and, further, in that its labeling failed to bear adequate directions for use in the aforesaid diseases, symptoms, and conditions for which the device was intended to be used and for which it was recommended and suggested in its advertising, disseminated and sponsored by and on behalf of the manufacturer and distributor.

DISPOSITION: J. C. Rabourn and Ada Rabourn, claimants, having filed an answer denying the material allegations of the libel, the case came on for trial before the court on November 16, 1948. The trial was concluded on the same day, and the case was taken under advisement by the court. On February 14, 1949, the court handed down the following findings of fact and conclusions of law:

BROADDUS, *District Judge:*

FINDINGS OF FACT AND CONCLUSIONS OF LAW

"1. The United States brings this action on libel of information for confiscation of two devices manufactured and sold for use as colonic irrigators, under the name of Tox Eliminator. The devices were shipped in interstate commerce from the manufacturer, Tox Eliminator Company in Glendale, California, to the claimants, Dr. J. C. Rabourn and Dr. Ada Rabourn, in Poteau, Oklahoma, within the Eastern District of Oklahoma, where the devices were seized. The articles are alleged to have been misbranded within the provisions of section 301 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. A. 331). This court has jurisdiction. 21 U. S. C. A. 334; 28 U. S. C. A. Sept. 1, 1948) sec. 1356.

"2. The Tox Eliminator is a device consisting of certain pipes, tubes, faucets and accessories offered for sale and sold to be used as a colonic irrigator and providing for controlled irrigation of the colon by water. The device was manufactured and sold by the Tox Eliminator Company of Glendale, California. The agent of the company in Oklahoma was one Mr. Fred McCabe.

"3. The company had forwarded by mail from Glendale to McCabe in Oklahoma two pamphlets entitled 'The Magic Power of Water' and 'The Modern Scientific Drugless Way to Health,' and a letter to be used as a circular letter, addressed to 'My dear friend.' These pamphlets advertising the Tox Eliminator contained representations as to its curative power. McCabe made a sale of one of the devices to a doctor in Sulphur shortly before the sale of the Tox Eliminators here considered. Using the original pamphlets

and letter that he had received from California he had identical printed copies thereof made in Shawnee, the only change being the name of the doctor, and these were used and distributed in connection with the Sulphur sale.

"4. Two of the devices were sold by McCabe in September of 1946 to the Rabourns, the claimants in this case. The devices were thereafter shipped in interstate commerce from Louisville, Kentucky, to which city they had been shipped from Glendale, California, and stored, to Poteau, Oklahoma, in December of 1946 and delivered to the Rabourns. At the time of the sale it was agreed as a part of the contract of sale that McCabe would conduct a scheme of advertisement and promotion of the devices by causing the pamphlets and letters, in the form furnished to McCabe by the company and heretofore identified, to be mailed to a list of prospective patients in the vicinity of Poteau, Oklahoma, to induce them to seek treatments by the use of the devices in the office of the claimants. The literature was examined by the Rabourns and, upon their approval, copies of the pamphlets and the circular letter received by McCabe from the company in Glendale, or copies of the former Shawnee printing of the same literature were reproduced or printed, in Shawnee and mailed by a local mailing agency to some two thousand persons of a prepared list of prospective patients. The Rabourns reimbursed McCabe for this expense as agreed in the sales contract.

"5. The literature mailed made claims as to the effectiveness of the machine in the cure or relief of many of the ills that affect the human body. Though it is admitted by the claimants that these claims are false, they assert that the government may not successfully proceed in this libel of information because the literature in question under the facts was not a labeling of the devices as it was not (1) upon the device sold and shipped in interstate commerce or (2) did not accompany such device within the meaning of the Federal Food, Drug and Cosmetic Act (21 U. S. C. A. Sec. 321 et seq.).

"A. The Federal Food, Drug and Cosmetic Act (21 U. S. C. A. Sec. 321, et seq.) is primarily for the protection of the public and should receive a liberal construction. United States v. Dotterweich, 320 U. S. 277; Pasadena Research Laboratories, Inc. v. United States, 9 Cir., 169 F. 2d 375; Arner Co. v. United States, 1 Cir., 142 F. 2d 730; United States v. Research Laboratories, 9 Cir., 126 F. 2d 42.

"B. As the literature used makes false claims of the curative value and effectiveness of the device, it is a misbranding if such literature be considered to be a part of the labeling under the provisions of the statute. 21 U. S. C. A., Sec. 352 (a); United States v. One Device, 10 Cir., 160 F. 2d 194. 'Labeling' means all labels and other written, printed or graphic matter upon any article or its container or wrapper; or accompanying such article. 21 U. S. C. A. Sec. 321 (m). The circular and pamphlets not being upon or attached to the devices or their containers or wrappers, the inquiry is whether such matter accompanied the devices within the purview of the section. The phrase 'accompanying such article' is not restricted to 'labeling' that is on the article of package forwarded in interstate commerce. As used in the Act, 'accompanying' described the relationship between the article and its labeling. The accompaniment is one of commercial association. An article or device is accompanied by labeling when the labeling supplements or explains the use of the article. Kordel v. United States (not officially reported) No. 30, October Term, Nov. 22, 1948, United State v. Kordel, 7 Cir., 164 F. 2d 913; United States v. Kordel, D. C. N. D. Ill., 66 F Supp. 538; United States v. Lee, 7 Cir.,

131 F. 2d 464; United States v. Paddock, D. C. W. D. Mo., 68 F. Supp. 407; United States v. 7 Jugs, etc., D. C. Minn. 53 F. Supp. 746.

"Here both the literature and the device originated in California, the device being shipped in interstate commerce and the original or copy of the literature being sent from California to Oklahoma by mail to be subsequently used as the pattern or copy for the pamphlets and circulars sent out pursuant to the sales agreement. It was 'an accompanying' within the meaning of the Act. To hold otherwise would be to permit an escape from purpose of the Act by the plainest sort of subterfuge.

"C. Nor does the fact that the literature was distributed for advertising purposes prevent it from being 'labeling' as defined by the Act. U. S. v. Kordel, 7 Cir., supra; United States v. Paddock, D. C. W. D. Mo., 67 F. Supp. 819.

"6. The only labels attached to the devices are the respective name plates, each with the words 'Tox Eliminator, Tox Eliminator Company, Inc., Glendale, California, Serial No. ——.' The government contends that should the circulars be held not to be labeling within the concept of the Federal Food, Drug and Cosmetic Act then the devices are misbranded because of the insufficiency of the labeling.

"7. As a part of the sales agreement it was agreed that soon after the delivery of the machines the company would conduct a clinic called a 'health clinic' to introduce the machines to the public. A licensed chiropractor of California, not licensed to practice the healing art in Oklahoma, was sent from California office of the Tox Eliminator Company to demonstrate the device and assist in the holding of the clinic. He gave a short course of instruction to the Rabourns so they might understand the operation of the devices and he assisted in the giving of treatments with the devices. Following this clinic and instruction, like treatments were given under the supervision of either of the Rabourns in their offices.

"D. A device shall be deemed to be misbranded unless its labeling bears adequate directions for use provided where such requirement as applied to such device is not necessary for the protection of the public health the Administrator shall promulgate regulations exempting such device from the requirement. 21 U. S. C. A. Sec. 352 (f) (1).

"E. The Federal Security Administrator is authorized to promulgate regulations for the efficient enforcement of the law (21 U. S. C. A. Sec. 371 (a)); and such regulations may be interpretive of the statute in so far as they do not conflict with or add to the provisions of the law. United States v. Antikamnia Chemical Co., 231 U. S. 654; 666; Arner v. U. S., 1 Cir., 142 F. 2d 730, certiorari denied 323 U. S. 730. Under such authority the Administrator has adopted regulations not inconsistent with his powers providing that directions for use may be inadequate by reason of omission in whole or in part of incorrect specifications of directions for use in all conditions for which devices are prescribed, recommended or suggested in the labeling or advertising disseminated or sponsored by its manufacturer or packer, or in such other conditions as said device is commonly or effectively used. 21 Code of Federal Regulations, Cum. Supp., Sec. 2.106 (a) (1). The label on the device containing the words 'Tox Eliminator' standing alone is not a misbranding as the device tends to remove toxins (U. S. v. One Device, supra) but in the light of Regulations Sec. 2.106 (a) (1) the branding is inadequate because the words on the devices do not include all the claims for the curing or treatment set out in the advertising circulars. United States v. 150 Packages

Bush Mulso Tablets, Civil No. 4415, D. C. E. D. Mo. (not officially reported); United States v. 516 Cases Nue-Ovo, D. C. S. D. Cal. No. 7418-C, 1948 (not officially reported). The devices were misbranded unless exempted by some other provision of the law or regulations made pursuant thereto.

"8. As to many of the diseases and conditions referred to in the circulars the devices are of no benefit as a cure and afford no relief. To such an extent the claims and implications of the circulars are false and misleading.

"F. Exempted from the requirement of Sec. 352 (f) (1) of the statute (except as otherwise provided by paragraph (h) and (i) of Sec. 2.106 of the regulation) is the delivery or shipment of a device complying with certain conditions, among which conditions are that adequate information for the use of the device by a physician is readily available (Code of Federal Regulations, Supp. 1944, Sec. 2.106 (b) (5) (i)); and that the shipment or delivery complies with all the conditions set forth in paragraphs (b) (3) of such regulatory section and is made to a physician to be dispensed by or under the direction of a physician in his professional practice (Code of Federal Regulations, Supp. 1944, Sec. 2.106 (e)). The effect of the regulation in application to the facts of this case is that the shipment or delivery of the device is exempted from Sec. 352 (f) (1) of the statute if adequate information for the use of the device by a physician is readily available; and it is made to a physician to be dispensed by or under the direction of a physician. That the devices were delivered to physicians to be dispensed under the direction of such physicians is clear. There remains the question of whether adequate information for the use of the device by a physician is readily available. The adequate information required relates to the use of the machine in the treatment of the diseases and conditions for which it is intended to be used, as set forth in the circulars. Such adequate information must be readily available. While it may be possible that harm or injury might not result in certain instances from use of the devices under the supervision of chiropractors, the exemption from the requirement of the statute may not be allowed for that reason standing alone. It is within the spirit and intent of the statute that the public be protected from fraudulent representations of the curative or beneficial result to be secured from the use of a device; and the words in the exemption of the regulation that 'adequate information for the use of the device by a physician be readily available' embraces the concept of truthful and adequate information of its use to bring about probable cure of or some relief from the diseases and conditions contained in the circulars and advertisements. As many of the claims of the circulars have no basis in fact, adequate information for their use may not be considered as readily available. Were it otherwise the probable harm from the use of the devices for conditions or diseases or the delay in securing relief by other means might find justification never contemplated but intended to be denied by the broad purposes of the statute.

"Judgment of condemnation will be entered as of the date of the filing of these findings of fact and conclusions of law, this the 14th day of February, 1949, and the machines will be delivered to the proper authorities for disposition as provided by law."

In accordance with the foregoing findings of fact and conclusions of law, judgment of condemnation was entered as of February 14, 1949, and the devices were ordered destroyed.