

"Section 503 (a) does not state the exemption. 'It authorizes the formulation of the exemption by regulations. Therefore, unless contrary to law, arbitrary, or unreasonable, the terms of the exemption can be prescribed in the discretion of the administration'. See Hoge: *An Appraisal of the New Drug and Cosmetic Legislation*, 6 Law and Contemporary Problems 116. Had Congress intended an outright exemption of bulk shipments from the labeling requirement without restrictive terms of any sort, there would have been no need for it to provide for regulations formulating the exemption; the law would have simply stated the exemption. The agreement containing specifications for the labeling of the drugs as provided in regulation (a) (2) serves the same purposes of facilitating the enforcement of the Act as was indicated by the Supreme Court in *McDermott v. Wisconsin*, *supra*, to be the purpose served by a label on a retail article before the article is sold. Applied to a situation like the case at bar it would aid in the detection and proof of adulteration in the shipment from the manufacturer to the proprietor of the formula. Cf. *Strong, Cobb & Co., Inc. v. United States*, *supra*. There is no hindrance to honest business in this requirement. The instrument⁵ which is here purported to be such an agreement is neither signed by the shipper nor does it contain any specifications for the labeling as required by the regulation (a) (2). Obviously such an instrument does not serve the useful function indicated above and was intended for some purpose entirely foreign to the regulation.

"Regulation (a) (1) is not applicable to this case. It pertains to a case where the repacker and the person shipping the article to be repacked are one and the same person with plants in different states. See Toulmin, *Law of Food, Drugs and Cosmetics* (1942) p. 322, § 173. There is no danger in such a case of the repacker unwittingly passing on adulterated drugs to the ultimate consumer. The regulation does not exempt a repacker who introduces the goods into commerce through an 'agent' designated for that purpose, which 'agent' was the vendor of the goods. This 'agency' of the Arner Company to ship the goods can no more bring the appellants within regulation (a) (1) than can it avoid the scope of interstate commerce as indicated by the cases cited in the earlier part of this opinion.

The decree of the District Court is affirmed.

The Arner Co., Inc., subsequently filed with the United States Supreme Court an application for a writ of certiorari, and on October 9, 1944, the application was denied.

1158. Misbranding of Fruitola, Traxo, and Abbott Bros. Compound. U. S. v. 8 Dozen Packages of Fruitola, 3½ Dozen Packages of Traxo, and 8 Packages of Abbott Bros. Compound. Decree of condemnation and destruction. (F. D. C. Nos. 6541 to 6543, incl. Sample Nos. 71321-E to 71323-E, incl.)

On December 18, 1941, the United States attorney for the Eastern District of Missouri filed libels against 8 dozen packages of Fruitola, 3½ dozen packages of Traxo, and 8 packages of Abbott Bros. Compound at St. Louis, Mo., alleging that the articles had been shipped on or about April 21 and September 29, 1941, from Monticello, Ill., by the Pinus Medicine Co.; and charging that they were misbranded.

Examination of the Fruitola disclosed that each package contained 4 powders in blue paper, 2 powders in white paper, and a bottle of a liquid. The powder in the blue paper consisted of sodium bicarbonate and Rochelle salt; the powder in the white paper consisted of tartaric acid; and the liquid in the bottle consisted essentially of olive oil and anise oil. The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which

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"Paul Case,
Sole Distributor Case Combination New Improved Method
for 'Rheumatic' Pains,
33 Hamilton St., Brockton, Mass.
April 28, 1939, Brockton, Massachusetts.

To The Arner Company, Inc., Pharmaceutical Chemists, Buffalo, New York.

I, the undersigned, Paul Case, whose address is 33 Hamilton St., Brockton, State of Massachusetts, hereby guarantee the Arner Company, Inc., of Buffalo, New York, that each shipment or other delivery hereinafter made of the drugs known or designed as my formula No. 1 and formula No. 2 is not adulterated or misbranded, as of the date of such shipment or delivery, within the meaning of the Federal Food, Drug and Cosmetics Act, and is not an article which may not under the provisions of sec. 505 of the act be introduced into commerce.

(signed) PAUL CASE, Owner."

created the impression that it would promote the proper elimination of waste in the intestinal tract and regulate the flow of bile; that the article designated as Traxo was a tonic and a stimulant to the digestive tract and its nerve system and, when used in conjunction with Fruitola, would increase the efficacy of Fruitola; and that the preparation designated as Abbott Bros. Compound was efficacious in the treatment of muscular pains in limbs, sides, and back, rheumatism, neuritis, arthritis, sciatica, lumbago, and gout. It was alleged to be misbranded further (1) in that the name "Fruitola" and the reference to "fruit oils," appearing in the labeling, were false and misleading since they created the impression that the ingredients of the article were derived from fruits, whereas the ingredients of the article were not derived from fruits as commonly understood but consisted of sodium bicarbonate, Rochelle salt, tartaric acid, olive oil, and anise oil; and (2) in that the required statements of the active ingredients and of the quantity of contents of the article did not appear in its labeling in such terms as to render them likely to be understood by the ordinary individual under customary conditions of purchase and use, since the declaration of the active ingredients and the statement of the quantity of the contents were not set forth in a manner that made it clear that the carton contained two different preparations, one of which the manufacturer designated as "fruit oils" and the other as "compound effervescent powder."

Examination of the Traxo disclosed that it consisted essentially of alcohol, water, and extracts of plant materials including emodin, podophyllin, and strychnine. It was alleged to be misbranded because of false and misleading statements appearing in its labeling which created the impression that the article was a tonic and a stimulant to the digestive tract and its nerve system; that the preparation designated as Fruitola would increase the efficacy of Traxo; and that the preparation designated as Abbott Bros. Compound was efficacious in the treatment of muscular pains in the limbs, sides, and back, rheumatism, neuritis, arthritis, sciatica, lumbago, and gout.

Examination of Abbott Bros. Compound disclosed that it consisted essentially of water, alcohol, sodium salicylate, sodium phosphate, potassium nitrate, extracts of plant materials, and flavoring materials. It was alleged to be misbranded because of false and misleading statements appearing in its labeling which created the impression that it was a treatment for muscular aches and pains in the limbs, sides, and back; that Fruitola would promote the proper elimination of waste in the intestinal tract and regulate the flow of bile; and that Traxo was a tonic and a stimulant to the digestive tract and its nerve system. It was alleged to be misbranded further in that the article, when used as directed, would act as a laxative, and its labeling failed to warn the user that it should not be taken when suffering from nausea, vomiting, abdominal pains, or other symptoms of appendicitis, and that frequent or continued use of a laxative may result in dependence on a laxative.

On March 16, 1943, the sole intervenor having withdrawn its claim and answer, judgments of condemnation were entered and the products were ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

1159. Adulteration of Hart's Compound Asthma Medicine. U. S. v. 86 Bottles and 138 Bottles of Hart's Compound Asthma Medicine (and 17 other seizure actions against the same product). Default decrees of condemnation and destruction. (F. D. C. Nos. 10252, 10312, 10356, 10678, 10679, 10692, 10720 to 10722, incl., 10799, 10955, 10989, 10990, 10994, 10998, 11121, 12080 12115. Sample Nos. 8311-F, 11260-F, 16099-F, 16100-F, 21906-F, 21907-F, 21910-F, 21948-F, 22086-F, 22087-F, 34240-F, 35534-F, 36457-F, 38751-F, 48206-F to 48208-F, incl., 48232-F, 48233-F, 48240-F, 50336-F to 50338-F, incl., 51393-F to 51395-F, incl., 51602-F, 58937-F, 58938-F, 58944-F, 58945-F.)

Between July 15, 1943, and March 30, 1944, the United States attorneys for the Western District of Pennsylvania, the Northern Districts of California, Indiana, West Virginia, and Ohio, the District of Minnesota, the District of Utah, the District of Massachusetts, the District of Colorado, the Western District of North Carolina, and the District of Maryland filed libels against the following quantities of the above-named product, packed in containers of 2-fluid-ounce, 4-fluid-ounce, and 6-fluid-ounce sizes: 224 bottles at Uniontown, Pa., 117 bottles at San Francisco, Calif., 73 bottles at South Bend, Ind., 21 bottles at Minneapolis, Minn., 123 bottles and 59 packages at Cleveland, Ohio, 70 packages at Wheeling, W. Va., 85 packages and 71 bottles at Pittsburgh, Pa., 71 packages