The article was alleged to be misbranded (1) in that its labeling failed to bear adequate warnings against use and against unsafe methods of application, since the article contained carbolic acid, and its labeling failed to warn that a bandage should not be used when the article was applied to fingers and toes, and that the article should not be applied to large areas of the body; (2) in that its label failed to bear an accurate statement of the quantity of contents since the labels on the bottles containing the article represented that they contained 1 ounce, whereas the bottles contained less than that amount; and (3) in that the statements on its label which represented and suggested that the article was an all-purpose ointment and would be efficacious in the cure, mitigation, or treatment of all burns, cuts, sores, and all other skin disorders, were false and misleading since the article was not an all-purpose ointment and would not be useful in many conditions for which other ointments are used, and would not be an efficacious treatment for the more serious burns or cuts, or for sores or the numerous varieties of skin disorders.

It was alleged to be misbranded further because of false and misleading statements on its labeling in regard to the "Kru-Lax," which represented and suggested that the Kru-Lax contained no drugs and would be efficacious for the purposes described below.

Analysis of the Kru-Lax disclosed that it consisted essentially of plant material including laxative drugs, Epsom salt, and small proportions of buchu, licorice, gentian, anise, and sulfur.

It was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it contained no drugs and would be efficacious in the cure, mitigation, treatment, or prevention of dizziness, indigestion, tired feeling, colic, stomach trouble, foul breath, loss of appetite, coated tongue, rheumatism, and a great majority of human ailments; that it would be efficacious in the treatment of biliousness and of conditions of the system where a gentle stimulus to the action of the bowels was desired; that it would give immediate relief in conditions arising from inactivity of the liver; that it would make the user snap back to the feeling of "rarin to go" fitness; that it would eliminate the left-over wastes that hold one back; and that it would be efficacious to make weak bowels healthy and restore their muscular contraction. The article was alleged to be misbranded further in that its labeling failed to bear adequate directions for use, since the directions on the carton, "Dose: Take regular at bedtime, one-third teaspoonful in one-fourth glass water," and "In taking Kru-Lax start with one-third teaspoonful * * * on the following day, if it causes more than two evacuations, reduce the dose accordingly, or it may be increased if necessary," implied that the article should be taken repeatedly or continuously, whereas the article was a laxative and should not be used repeatedly or continuously since such use might result in dependence upon laxatives to move the bowels.

On March 7, 1944, the defendant having entered a plea of guilty, the court imposed a fine of $100 on each of 2 counts and sentenced the defendant to serve 6 months in jail. The jail sentence was suspended and the defendant was placed on probation for 3 years.

1157. Misbranding of Special Formula Tablets #2. U. S. v. 1 Drum of Special Formula Tablets #2. Tried to the court. Judgment for the Government. Decree of forfeiture and destruction. Judgment affirmed on appeal to the Circuit Court of Appeals. Application for writ of certiorari denied by the Supreme Court. (F. D. C. No. 5800. Sample No. 51270-E.)

On September 22, 1941, the United States attorney for the District of Massachusetts filed a libel against 1 drum containing 99,940 tablets of the above-named product at Boston, Mass., alleging that the article had been shipped on or about July 3 and August 7, 1941, from Buffalo, N. Y., by the Arner Co., Inc.; and charging that it was misbranded.

Analysis disclosed that the article contained an extract of a laxative plant drug such as cascara sagrada, sodium bicarbonate, and sodium citrate.

The article was alleged to be misbranded (1) in that its label failed to bear the common or usual names of the active ingredients in the preparations; (2) in that its labeling bore no directions for use; and (3) in that its labeling failed to bear adequate warnings, since the labeling did not warn the purchaser that the use of the article in case of abdominal pain, nausea, vomiting, or other symptoms of appendicitis might be dangerous and that frequent or continued use of the article might result in dependence upon laxatives to move the bowels.

On March 31, 1943, Paul Case, Brockton, Mass., and the Arner Co., Inc., having appeared as claimants, and the case having been submitted to the court on an agreed statement of facts, the following opinion was handed down by the court:

SWEENEY, *District Judge:* "This is a libel for the condemnation of certain drugs described in the libel as Special Formula Tablets No. 2. Paul Case has filed an answer asserting ownership of the goods seized. The Arner Co., Inc., in its answer, asserts that as agent for Case it shipped the goods in two large drums, and at the time of shipment it had in its possession a duly executed guarantee from Case that the drugs shipped would be packaged and labeled to conform to the law before sale to the consumer. The parties have agreed on the facts, and the real question of law is whether this shipment was exempt under the regulations.

"The tablets were manufactured in Buffalo, New York, by The Arner Co., Inc., for Paul Case of Brockton, Massachusetts, under a special formula owned by Case. They were labeled Special Formula Tablets No. 2 upon shipment, and, at all times thereafter and when seized, were in the container in which they had been shipped, and were not packed for retail sale. They were received by Case, and it was upon his premises that they were seized under 21 U. S. C. A. § 334 by the United States Marshal, who found one drum containing about 40,000 tablets of Special Formula No. 2. The parties agree that a representative sample of the tablets shows them to be 'sugar coated tablets containing sodium citrate, sodium bicarbonate and extract of a plant drug, such as cascara sagrada.' The Arner Co., Inc., is not the operator of the establishment where the tablets were to be labeled or repackaged.

"The case is one of first impression. The claimants contend that they are not required by the law to label the drugs, because they are in bulk. The statute requires all shipments to be properly labeled, and a special exemption for goods in bulk would not have been made in Section 353 (a), (21 U. S. C. A. § 353 (a) if bulk packages were not covered by the Act. *Strong, Cobb & Co.* v. *United States*, 103 F 2d 671, was a prosecution under the old Pure Food and Drug Act for drugs shipped in bulk. The present law is no narrower.

"There are two exemptions in Regulations § 2.107 (a) under Section 353 (a), 21 U. S. C. A. § 353 (a). The first is where the person who introduces the goods into interstate commerce is the operator of the establishment where the goods are to be repackaged. It is to be noted that the Regulation is addressed to the shipper and not the operator of the establishment. The Arner Co., Inc., manufactured and shipped the goods, and admits it is not the operator of the establishment where the drugs were to be repacked. Case claims that he introduced the goods into commerce through his agent, The Arner Co., Inc. There is no exemption in the regulations where the operator of the establishment that repacks introduces the goods into interstate commerce through an agent designated for that purpose. The exemption is to a qualified shipper, and the only shipper who can qualify is one who is the operator of the repacking plant. Further, the commercial agency of The Arner Co., Inc., to ship the goods was not such an agency as a law whose purpose is to guard the public health can notice. It does not avoid the scope of interstate commerce. *Santa Cruz Fruit Packing Company* v. *National Labor Relations Board*, 303 U. S. 453.

"The second exemption requires an agreement between the parties 'containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling or repacking.' The agreement submitted by the claimants contains no specifications as to the label on the retail package, and cannot be said to conform to the Regulation.

"I conclude that the seized shipment was not within the exempted classes, and, accordingly, was liable to seizure and forfeiture.

"A decree in accordance with the above may be submitted."

On April 6, 1943, judgment of forfeiture was entered and the product was ordered destroyed. Notice of appeal was filed by the claimants on April 13, 1943, and on May 4, 1944, the United States Circuit Court of Appeals for the First Circuit handed down the following opinion which affirmed the judgment of the District Court:

MAHONEY, J.: "This is a libel for the condemnation of certain drugs alleged to have been misbranded in violation of the Act of Congress of June, 1938, c.

675, 52 Stat. 1040, 21 U. S. C. §§ 301–392, known as the Federal Food, Drug, and Cosmetic Act. The drugs were manufactured in Buffalo, New York, by The Arner Co., Inc., for Paul Case of Brockton, Massachusetts, under a special formula owned by Case and were shipped f. o. b. from Buffalo by Arner to Case in Brockton where they were seized on the premises of the latter while in the bulk package in which they had been shipped. The package, a drum of about 40,000 tablets, was labeled 'Special Formula Tablets No. 2—The product contained herein must be packaged and labeled at point of destination before sale.' The drugs were to be repackaged by Case for the retail trade. The libel alleged that the drugs were misbranded in that the label did not contain the required names of the active ingredients of the preparation and contained no statement of warning and directions. The appellants denied that the drugs were misbranded and asserted that they were exempt from the labeling requirements of the Act as they were in bulk package, not retail packages and not intended for sale until repackaged and labeled. Paul Case, in his answer, asserts ownership of the goods. The Arner Company asserts that it shipped the goods as agent for Case and that at the time of shipment it had in its possession a duly executed guarantee from Case that the drugs shipped would be packaged and labeled to conform to the law before sale to the consumer. It is agreed that the composition of said Special Formula Tablets No. 2 is as follows: sugar coated tablets containing sodium citrate, sodium bicarbonate and extract of a plant drug, such as cascara sagrada. The Arner Company is not the operator of the establishment where the tablets were to be labeled or repackaged. The Arner Company and Paul Case here appeal from the decree of forfeiture. They contend (1) that 'labeling' as defined in the statute does not apply to containers of bulk shipments; (2) that regulation (a) (2) of § 503 (a) (21 U. S. C. § 353) is invalid because it exceeds the limitations of the statute; (3) that if said regulation is not invalid, it has been sufficiently complied with; (4) that the bulk package herein involved is especially exempted under regulation (a) (1) of § 503 (a).

"Section 301 (a) (21 U. S. C. § 331) prohibits 'the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded'. By § 502 (21 U. S. C. § 352) it is provided that a drug shall be deemed misbranded: '(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein. . . .'[1]

"Section 201 (k) (21 U. S. C. § 321) in defining 'label' provides: 'The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.'

"Contrary to appellants' contention, this section does not indicate that the labeling requirement applies only to retail packages and not to bulk shipments. That could not be the proper interpretation in view of § 503 (a) which directs the Administrator to promulgate regulations exempting such shipments on certain conditions: 'The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such

[1] Also pertinent to the libel is: "(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. . . ."

drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.'

"The first clause of § 201 (k)—'The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article'—thus must refer to an immediate container of an article shipped in bulk as well as the retail package and the second clause in referring specifically to retail packages must be an extension of labeling requirements and not a limitation. If § 201 (k) were not intended to apply to bulk shipments, § 503 (a) would be purposeless and meaningless. There would be no need to provide for the promulgation of regulations exempting bulk shipments from labeling requirements under designated conditions if the labeling requirement applied only to retail packages in the first place.

"Appellants rely in large part on a case under the Food and Drugs Act of 1906, 34 Stat. 768, *United States* v. *Sixty-Five Casks Liquid Extracts*, 170 Fed. 449 (N. D. W. Va. 1909) affirmed on appeal by memorandum decision in *United States* v. *Knowlton Danderine Co.*, 175 Fed. 1022 (C. C. A. 4th, 1910). They contend (1) that the case was cited with approval in *Hipolite Egg Co.* v. *United States*, 220 U. S. 45 (1911), and (2) that it is squarely in point with the case at bar. The *Danderine* case was unsuccessfully relied on by the plaintiff in error in the *Hipolite Egg* case. The Supreme Court set forth that case as follows, pp. 52, 53: 'The articles involved in the first case were charged with having been misbranded and consisted of drugs in casks, which were shipped from Detroit, Michigan, to Wheeling, West Virginia, there to be received by the Knowlton Danderine Company in bulk in carload lots and manufactured into danderine, of which no sale was to be made until the casks should be emptied and the contents placed in properly marked bottles.

" 'It was contended that the articles, not having been shipped in the casks for the purpose of sale thus in bulk, but shipped to the owner from one State to another for the purpose of being bottled into small packages suitable for sale, and when so bottled to be labeled in compliance with the requirements of the act, were not transported for sale, and were therefore not subject to libel under § 10 of the act.

" 'The contention submitted to the court the construction of the statute. The court, however, based its decision upon the want of power in Congress to prohibit one from manufacturing a product in a State and removing it to another State "for the purpose of personal use and not sale, or for use in connection with the manufacture of other articles, to be legally branded when so manufactured;" and concluded independently, or as construing the statute, that the Danderine company, being the owner of the property, shipped it to itself and did not come within any of the prohibitions of the statute. The case was affirmed by the Circuit Court of Appeals, 175 Fed. 1022. The court, however, expressed no opinion as to the power of Congress. It decided that the facts did not exhibit a case within the purpose of the statute, saying: "No attempt to evade the law, either directly or indirectly or by subterfuges, has been shown, it appearing that the manufacturer had simply transferred from one point to another the product he was manufacturing for the purpose of completing the preparation of the same for the market. Under the circumstances disclosed in this case, having in mind the object of the Congress in enacting the law involved, we do not think the liquid extracts proceeded against should be forfeited. In reaching this conclusion we do not find it necessary to consider other questions discussed by counsel and referred to in the opinion of the court." '

"Additional facts not stated by the Supreme Court were that Parke, Davis & Co., under a contract with the Danderine Company, compounded the product in accordance with a formula, a trade secret owned by the Danderine Company, and caused it to be shipped to that company. Whether it was a part of the agreed statement of facts, or whether it was a conclusion from the terms of the contract, Parke, Davis & Co. were considered by the circuit court to be agents of the Danderine Company and not independent contractors in the manufacturing of the product. We cannot conclude the same, nor was it so argued to us at the hearing, as to the Arner Company here. In the facts before us, insofar as the manufacturing of the drug is concerned, Arner Company cannot be said to be mere agents. They compounded the drug as independent contractors and title passed at some time to Paul Case.

"As was mentioned above, the Supreme Court refused to sustain the plaintiff in error's position in the *Hipolite Egg* case, and the plaintiff in error there relied

on the *Knowlton Danderine* case. The facts in *Hipolite Egg Co.* v. *United States*, *supra*, p. 50, were these: the action was a libel under § 10 of the Act of 1906, 34 Stat. 768, '* * * against fifty cans of preserved whole eggs, which had been prepared by the Hipolite Egg Company of St. Louis, Missouri.

" 'The eggs before the shipment alleged in the libel were stored in a warehouse in St. Louis for about five months, during which time they were the property of Thomas & Clark, an Illinois corporation engaged in the bakery business at Peoria, Ill.

" 'Thomas & Clark procured the shipment of the eggs to themselves at Peoria, and upon the receipt of them placed the shipment in their storeroom in their bakery factory along with other bakery supplies. The eggs were intended for baking purposes, and were not intended for sale in the original, unbroken packages or otherwise, and were not so sold. The Hipolite Egg Company appeared as claimant of the eggs, intervened, filed an answer, and defended the case, but did not enter into a stipulation to pay costs.

" 'Upon the close of libellant's evidence, and again at the close of the case, counsel for the Egg Company moved the court to dismiss the libel on the ground that it appeared from the evidence that the court, as a Federal court, had no jurisdiction to proceed against or confiscate the eggs, because they were not shipped in interstate commerce for sale within the meaning of § 10 of the Food and Drugs Act, and for the further reason that the evidence showed that the shipment had passed out of interstate commerce before the seizure of the eggs, because it appeared that they had been delivered to Thomas & Clark and were not intended to be sold by them in the original packages or otherwise.'

"The decision of the Supreme Court affirming the decree of condemnation must be taken as in effect a disapproval of the doctrine of the *Danderine* case. As was said in *Strong, Cobb & Co.* v. *United States*, 103 F. (2d) 671, 673 (C. C. A. 6th, 1939): 'However, appellant maintains that under the doctrine of *United States* v. *Knowlton Danderine Co.*, 4 Cir., 175 F. 1022, there was in contemplation of law no shipment in interstate commerce under the Food and Drugs Act because the tablets were shipped in bulk, to be repackaged by the Scotch-Tone Company before retail distribution. The conclusive answer to appellant's contention is that the doctrine of the *Knowlton Danderine Co.* case has been in effect disapproved in *Hipolite Egg Co.* v. *United States*, 220 U. S. 45, 31 S. Ct. 364, 55 L. Ed. 364. In that case the Knowlton Danderine decision was relied on as supporting the proposition that Section 10 of the Food and Drugs Act, 21 U. S. C. A. § 14, does not apply to an article of food which has not been shipped for sale, but which has been shipped solely for use as raw material in the manufacture of some other product. The court, in discussing the proposition, states that the situations covered by the statute cannot be qualified "by the purpose of the owner to be a sale" and holds that the contention of the Egg Company is untenable.' See also *Philadelphia Pickling Co.* v. *United States*, 202 F. 150, 151–2, (C. C. A. 3rd, 1913).

"The appellant Arner Company argues that title to the drugs passed to Paul Case within the state of origin for transportation and that Arner Company acted merely as agent for Case in shipping the goods in interstate commerce, hence the shipment is not within the Act. Such argument cannot avail the appellants. The passing of title in the state of origin for transportation does not take the case out of the Act. *Hipolite Egg Co.* v. *United States*, *supra*; *United States* v. *Tucker*, U. S. D. C. S. D. Ohio, April 8, 1911 (reported in *Decisions of Courts In Cases Under The Federal Food and Drugs Act* by Mastin G. White and Otis H. Gates, at page 248).

"As was said in *Santa Cruz Fruit Packing Co. v. National Labor Relations Board*, 303 U. S. 453, 463 (1938): '. . . sales to purchasers in another State are not withdrawn from federal control because the goods are delivered f. o. b. at stated points within the State of origin for transportation. See *Savage* v. *Jones*, 225 U. S. 501, 520; *Texas & N. O. R. Co.* v. *Sabine Tram Co.*, 227 U. S. 111, 114, 122; *Pennsylvania R. Co.* v. *Clark Bros. Coal Mining Co.*, 238 U. S. 456, 465–468. A large part of the interstate commerce of the country is conducted upon that basis and the arrangements that are made between seller and purchaser with respect to the place of taking title to the commodity, or as to the payment of freight, where the actual movement is interstate, do not affect either the power of Congress or the jurisdiction of the agencies which Congress has established . . .' 'The Act is concerned not with the proprietory relation to a misbranded or an adulterated drug but with its distribution.' *United States* v. *Dotterweich*, 320 U. S. 277, 283 (1943).

"The appellants argue that although *Hipolite Egg Co.* v. *United States, supra,* and *Strong, Cobb & Co.* v. *United States, supra,* were cases holding bulk shipments within the earlier Act, those cases involved adulterated goods which, of course, would be harmful to the ultimate consumer. Since such consumer never will see the label on the bulk package, the argument runs, there is no protection to him in requiring such label and hence nothing in such a requirement facilitates the purposes of the Act.[2] The argument is based on the maxim that where the reason ceases (protection of consumer) the rule also ceases. The fallacy in this line of reasoning lies in a misconception of the functions of the label. In addition to advising the ultimate consumer, there are other purposes of a label: 'The label upon the unsold article is in the one case the evidence of the shipper that he has complied with the act of Congress, while in the other, by its misleading and false character, it furnishes the proof upon which the Federal authorities depend to reach and punish the shipper and to condemn the goods. If truly labeled within the meaning of the act his goods are immune from seizure by Federal authority; if the label is false or misleading within the terms of the law the goods may be seized and condemned. In other words the label is the means of vindication or the basis of punishment in determining the character of the interstate shipment dealt with by Congress.' *McDermott* v. *Wisconsin,* 228 U. S. 115, 132–133 (1913). If adulterated bulk shipments are within the purview of the act as established by the *Hipolite Egg* and *Strong, Cobb & Co.* cases, the requirement of labeling of bulk goods facilitates the detection and proof of such adulteration. Of course, enforcement of a labeling requirement could not be effective if the failure to meet the requirement were prosecuted only in the comparatively rare instances where the goods actually were adulterated.

"Another facet of the same argument is appellants' contention that since Paul Case supplied the formula for the drugs he knew what they were to contain and therefore any label indicating the contents would be superfluous. This argument overlooks the aforementioned functions of a label. If the drugs sent out by the Arner Company were of less strength than called for by the order, Paul Case might not detect this and might repack them in retail containers, misbranding them because the Arner Company had not properly filled his order, and the ultimate consumer would be getting a product which was adulterated within the meaning of the Act. If the bulk shipment were labeled, the Food and Drug administrators would be aided in detecting the adulteration since they could sample the bulk shipment and compare it with the label. In this way the administration of the Act would be facilitated. Adulteration could be detected in the early bulk stage before it ever got into retail channels.

"We turn now to a consideration of § 503 (a) which provides for regulations exempting bulk shipments from the labeling requirement:[3] 'Sec. 353(a). The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated

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[2] Since the regulations provided for by the Act exempt bulk goods from the labeling requirement on condition that certain information otherwise required on the label is set forth in an agreement, this argument would be more properly addressed to those regulations hereinafter considered.

[3] Sen. Rep. No. 493, 73rd Cong., 2d Sess., 1934, p. 9, accompanying S. 2800, one of the bills leading to enactment of the present law declared: 'Par. (c) authorizes the exemption from any labeling or packaging requirement of the bill articles which are, in accordance with the practice of the trade, processed, labeled, or repacked in substantial quantities at establishments other than those where they are originally processed or packed, on condition that the articles conform to the provisions of the bill at the time they leave the processing, labeling or repacking establishment. This exemption is necessary to avoid unwarranted interference with certain legitimate commercial operations, such as the canning of food at branch canneries and delivery to a central plant for labeling, or the bulk shipment of crude drugs for processing and repacking before distribution to consumers.'

In House Report No. 2139 (75th Cong., 3rd Sess., 1938) the following comment on section 405(2) of the bill in relation to exemption of labeling with respect to food appears (p. 6): "Section 405 authorizes exemptions from the labeling requirements of the act which are not provided by the present law but which have been permitted by administrative regulation. There is no necessity for labeling of any kind on most of the types of open containers of fresh fruits and fresh vegetables. In certain cases there is a very real need for the exemption of canned food and other food from labeling. For example, most of the salmon packed in Alaska is shipped unlabeled to Seattle, Portland, and San Francisco, and from these points distributed under appropriate label. The exemptions will apply only where the interests of consumers will not be jeopardized."

or misbranded under the provisions of this chapter upon the removal from such processing, labeling, or repacking establishment.' The pertinent regulation promulgated under this section provides: 'Regulation. [§ 2.107] (a) Except as provided by paragraphs (b) and (c) of this regulation, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501(b) and 502(b), (d), (e), (f), and (g) of the Act if—(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or (2) in case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Agency who requests them.' [4]

"The appellants contend that the Administrator went beyond the statute in requiring a written agreement containing specifications. Their contention is that § 503(a) requires regulations flatly exempting such bulk shipments from the labeling provision and providing no safeguarding conditions to such exemption. To so construe the section would 'read(s) an exception to an important provision safeguarding the public welfare with a liberality which more appropriately belongs to enforcement of the central purpose of the Act'. *United States* v. *Dotterweich*, 320 U. S. 277 (1943). The Supreme Court thus clearly indicated in the *Dotterweich* case what must be our guide in construing the Act. As Mr. Justice Frankfurter said: 'The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. See *Hipolite Egg Co.* v. *United States*, 220 U. S. 45, 57, and *McDermott* v. *Wisconsin*, 228 U. S. 115, 128. * * * Nothing is clearer than that the later legislation was designed to enlarge and stiffen the penal net and not to narrow and loosen it. This purpose was unequivocally avowed by the two committees which reported the bills to the Congress. The House Committee reported that the Act "seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906". (H. Rep. No. 2139, 75th Cong., 3rd Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation "must not weaken the existing laws", but on the contrary "it must strengthen and extend that law's protection of the consumer". (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1).'

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[4] The remainder of this regulation provides:

"(b) An exemption of a shipment or other delivery of a drug or device under clause (1) of paragraph (a) of this regulation shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void *ab initio* if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed. . . ."

"(d) An exemption of a shipment or other delivery of a drug or device under clause (2) of paragraph (a) of this regulation shall expire—

"(1) at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

"(2) upon the refusal by the operator of the establishment where such drug or device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause."

"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 instrument [5] 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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[5] "Paul Case,
Sole Distributor Case Combination New Improved Method
for 'Rheumatic' Pains,
33 Hamilton St., Brockton, Mass.
April 28, 1939, Brockton, Massachusettts.

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."