1380. Misbranding of Nue-Ovo. U. S. v. 143 Packages of Nue-Ovo. Judgment of dismissal in the district court reversed by circuit court of appeals. Petition for writ of certiorari denied by the Supreme Court. Case returned to the district court and tried to the jury. Verdict for the Government. Decree of condemnation and destruction. (F. D. C. No. 1909. Sample No. 16224–E.)

On May 6, 1940, the United States attorney for the Western District of Missouri filed a libel against 143 packages, each containing 3 bottles, of Nue-Ovo at Kansas City, Mo., alleging that the article had been shipped on or about March 15, 1940, from Chicago, Ill., by Nue-Ovo, Inc.; and charging that it was misbranded in that the statements in its labeling, i. e., in the circular entitled "What is Arthritis" accompanying the article, were false and misleading since they represented and suggested that the article was a competent treatment for arthritis, whereas it was not.

Analysis disclosed that the article consisted essentially of extracts of plant drugs, including kola nut, sugars, and water, preserved with sodium benzoate.

On July 11, 1940, the Research Laboratories, Inc., Portland, Oreg., having appeared as intervenor and having filed a motion for removal of the case, an order was entered directing that the case be removed to the Western District of Washington for trial. Thereafter, the intervenor filed exceptions to the libel on the ground (1) that the libel failed to state how and in what manner the Government claimed that the circular accompanied the article; and (2) that the libel failed to state in what particulars the Government claimed the labeling to be false and misleading. Thereafter, the matter came on for hearing before the court, and on December 4, 1940, an order was entered allowing the exceptions and directing that the libel be amended accordingly.

In accordance with this order, an amended libel was filed on or about December 7, 1940, the material allegations of which are set forth hereinafter in the opinion of the circuit court of appeals. Subsequently, the intervenor filed exceptions to the amended libel, and on June 2, 1941, after due consideration of the briefs and arguments of counsel, the court sustained that exception which challenged the sufficiency of the amended libel, and ordered the dismissal of the action. Thereafter, a motion for leave to file a second amended libel was made on behalf of the Government, and on June 16, 1941, an order was entered denying that motion. The case was then taken on appeal to the Circuit Court of Appeals for the Ninth Circuit, and on February 24, 1942, the following opinion was handed down by that court:

MATHEWS, *Circuit Judge:* "In the District Court of the United States for the Western District of Missouri, 143 packages of a drug called Nue-Ovo were proceeded against by appellant, the United States, on a libel for condemnation under § 304 (a) of the Federal Food, Drug and Cosmetic Act,[1] 21 U. S. C. A. § 334 (a). On application of appellee, Research Laboratories, Incorporated, claimant of the 143 packages of Nue-Ovo, the proceeding was removed to the District Court of the United States for the Western District of Washington. In that court appellant was ordered to, and did, amend its libel. To the amended libel (hereafter called the libel) appellee filed exceptions, one of which was that the libel 'fails to state facts sufficient to constitute a cause of action.' This exception was sustained and the proceeding was dismissed. From the order of dismissal this appeal is prosecuted.

"The libel is crudely and inexpertly drawn. It does not state directly and positively, as a competently drawn libel would have stated, that the 143 packages of Nue-Ovo were misbranded when introduced into or while in interstate commerce. It does, however, state:

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[1] Section 304 (a): "Any article of food, drug, device, or cosmetic that is * * * misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on information and condemned in any district court of the United States within the jurisdiction of which the article is found: Provided, however, That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, [with inapplicable exceptions]. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court * * * shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial."

That the said article [Nue-Ovo][2] is misbranded in violation of the Federal Food, Drug and Cosmetic Act * * * in that the statements appearing in the labeling thereof, viz., in the circulars entitled "What is Arthritis," accompanying the said article are false and misleading in this, that all and singular of the statement therein and the whole thereof create the impression in the mind of the reader thereof that the said article is a competent treatment for arthritis and excite a feeling of hope and expectation in the mind of a sufferer from arthritis that the use and consumption of said article will be beneficial in treatment of said disease, whereas the said article is not a competent and beneficial treatment for arthritis. * * *

That on or about the 15th day of March, 1940, the said 143 packages, more or less, each containing 3 bottles of an article labeled in part "Nue-Ovo" were shipped * * * in interstate commerce from Chicago, Illinois, by Nue-Ovo, Inc., Chicago, Illinois, * * * to Crown Drug Company, Kansas City, Missouri, and said article now remains unsold in the possession of the Crown Drug Company at Kansas City, Missouri.

That the said circular accompanied said article while in interstate commerce, and thereafter, in the following manner, to-wit:

That a shipment of circulars from Nue-Ovo, Inc., Chicago, Illinois, designated by title as "What is Arthritis" (Exhibit A)[3] and containing the same printed words, letters and form, were received in interstate commerce by the Crown Drug Company of Kansas City, Missouri, at its warehouse * * * in said city simultaneously with the said article; that the said circulars and the said shipment of "Nue-Ovo" were placed, then and there, in the same room of the said warehouse for distribution to retail stores of the said Crown Drug Company at Kansas City, Missouri * * *.

"Thus, in substance, the libel states that 143 packages of Nue-Ovo and printed circulars containing false and misleading statements concerning Nue-Ovo were shipped in interstate commerce from Chicago, Illinois, to Kansas City, Missouri, and that all the packages and all the circulars were so shipped by a single shipper (Nue-Ovo, Inc.) to a single consignee (Crown Drug Company) and were by said consignee simultaneously received in interstate commerce.

"These statements must, for present purposes, be taken as true. Taking them as true, we hold that the circulars accompanied the packages and constituted their labeling within the meaning of the Act;[4] that, since the circulars were false and misleading, the packages were misbranded within the meaning of the Act;[5] that, since the circulars accompanied the packages in interstate commerce, the packages were misbranded while in interstate commerce within the meaning of the Act; and that, therefore, the packages—and, of course, their contents—are subject to condemnation.

"The libel does not state, nor is it material, whether the packages and the circulars did or did not travel in the same crate, carton or other container or on the same train, truck or other vehicle during their interstate journey. The packages and the circulars had a common origin and a common destination and arrived at their destination simultaneously. Clearly, therefore, they accompanied each other, regardless of whether, physically, they were together or apart during their journey.

"Appellee contends that the circulars constituted advertising and, therefore, did not constitute labeling within the meaning of the Act. The contention assumes that printed matter (such as a circular) cannot constitute both advertising and labeling. The assumption is unwarranted. Most, if not all, labeling is advertising. The term 'labeling' is defined in the Act as including all printed matter accompanying any article.[6] Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.

"The rule of strict construction invoked by appellee has little or no application to statutes designed, as the Federal Food, Drug and Cosmetic Act is designed, to prevent injury to the public health. A. O. Andersen & Co. v. United States, 9 Cir., 284 F. 542, 543; United States v. 48 Dozen Packages of Gauze, 2 Cir., 94 F. 2d 641, 642.

"It is immaterial, if true, that the makers and advertisers of Nue-Ovo could have been proceeded against by the Federal Trade Commission under the Federal Trade Commission Act and could have been ordered to cease and desist from publishing and distributing the circular entitled 'What is Arthritis.' The

[2] The libel does not call Nue-Ovo a drug, but calls it an article. It nevertheless appears from the libel that Nue-Ovo is intended for use in the treatment of disease in man and hence is a drug within the meaning of the Act. See § 201 (g) of the Act, 21 U. S. C. A. § 321 (g). Appellee's brief concedes that Nue-Ovo is a drug.

[3] Exhibit A—a copy of the circular entitled "What is Arthritis"—is attached to the libel. The gist of the circular is that Nue-Ovo is a competent and beneficial treatment for arthritis.

[4] Section 201 (m) of the Act, 21 U. S. C. A. § 321 (m), defines the term "labeling" as meaning "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

[5] Section 502 of the Act, 21 U. S. C. A. § 352. provides:

"A drug or device shall be deemed to be misbranded—

"(a) If its labeling is false or misleading in any particular."

[6] See footnote 4.

power of the District Court to condemn misbranded articles is not impaired, diminished, or in any wise affected by the possibility that such misbranding may also be the subject of a cease and desist order or even by the fact, if it be a fact, that such an order has actually issued.

"There is no merit in appellee's contention that the libel does not sufficiently charge that the circular entitled 'What is Arthritis' is false and misleading. The circular states, in substance and effect, that Nue-Ovo is a competent and beneficial treatment for arthritis. The libel charges that it is not, and that, therefore, the circular is false and misleading. No other charge is necessary.

"Order reversed."

A petition for rehearing was filed by the intervener and was denied by the court on April 2, 1942; and on April 9, 1942, a mandate issued remanding the case to the district court. A petition for writ of certiorari to the United States Supreme Court by the intervener was denied on October 12, 1942, following which the intervener filed an answer to the amended libel, denying that the article was misbranded. The case was tried to a jury, and on June 16, 1943, a verdict for the Government was returned. A proposed decree of condemnation providing for destruction of the product was submitted to the court by the Government. Upon objection by the intervener, the matter was taken under advisement by the court, and, after consideration of the briefs of the parties, the following memorandum opinion was handed down:

LEAVY, *District Judge:* "This is a libel proceeding instituted by the United States of America under the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A., against 143 packages, more or less, each containing three bottles of a proprietary medicine called 'NUE-OVO', which were claimed by Research Laboratories, Inc., as being their property.

"The method of labeling in this case was novel and unusual in practice. The sufficiency of the government's libel of information was attacked by the intervenor herein on the ground that it did not state facts sufficient to show a violation of the Federal Food, Drug and Cosmetics Act. After amendment by the government of its original libel of information, the attack was renewed upon the same grounds, and the intervenor's motion to dismiss was sustained by the District Court. Thereupon, the government appealed, and the holding of the District Court was reversed and the cause remanded for trial upon the allegations of the amended libel and the issues made by the further pleadings of the intervener. U. S. v. Research Laboratories Inc., 126 Fed. 2nd 42.

"Trial upon the issues as made by the pleadings was by jury, resulting in a verdict finding for the government in its contention that the articles were misbranded by reason of the labeling thereof being false and misleading.

"Following the receipt and entry of the verdict herein, plaintiff submitted, upon notice, a form of judgment and decree of forfeiture and condemnation, providing that the United States Marshal shall destroy the said 143 packages of 'Nue-Ovo'.

"At the time fixed by the notice for the presentation of the judgment, the intervenor, Research Laboratories, Inc., appeared and objected thereto, insisting that that part of the decree providing for the destruction of the libeled property should be stricken, and in lieu thereof, a provision made for the sale of the property. The parties requested and were given time to submit written briefs upon this issue.

"It is the contention of the intervenor, Research Laboratories, Inc., that under the facts as disclosed in this case, the court is without discretion to order the destruction of the property, and they contend further that if such discretion, as a matter of law, does exist, it would be an abuse thereof, as well as unjust and inequitable to order its destruction.

"The language of the Act is unambiguous, and clearly places it within the discretion of the court to dispose of the condemned property either by ordering its sale or destruction, so long as the disposition is in accordance with the provisions of the Act. 21 U. S. C. A. 334 (d).

"The conclusions reached here as to the discretionary power of the court in reference to the disposition of condemned property is supported by the following cases: U. S. vs. Two cans of Oil of Sweet Birch and Three Cans of Oil of Gaultheria, 268 Fed. 866. U. S. vs. 1443 Cases, More or less, Canned Salmon, 7 Fed. Supp. 77.

"In making a disposition of this matter, the court is bound by the facts as they were found by the jury, upon the issues submitted to it. The issue made by the pleadings and directly submitted by the court's charge to the jury for its consideration was whether there was a misbranding by reason of the labeling being false or misleading, and this, in turn, included the issue as to whether the

medicine involved herein had any value whatever in the beneficial treatment of arthritis in any of its forms.

"It was conceded by all parties that 'Nue-Ovo' was not injurious or harmful. The verdict of the jury is the equivalent of a finding:

"1. That the labeling of 'Nue-Ovo' was false and misleading.

"2. That the substance 'Nue-Ovo' was useless and valueless as a remedy in the treatment of arthritis.

"In passing upon the matter now before the court, therefore, it is not a question of what the court may think concerning the facts, but the facts that were found by the jury's verdict must be accepted, and since the jury has found that there was a misbranding by reason of false and misleading labeling, and also found that the article in question has no therapeutic value in the treatment of arthritis, it would be an abuse of discretion on the part of the court to direct its sale, and thus permit it to again become an article of commerce.

"The only purpose of placing 'Nue-Ovo' on the market was as a beneficial treatment for arthritis. The findings of the jury to the effect that it was not such treatment make it inconsistent to direct its sale and movement back into the channels of commerce and trade.

"I, therefore, overrule the objections interposed by the intervenor, Research Laboratories, Inc., and upon the re-submission of the judgment and decree of forfeiture and condemnation, the same will be signed."

On August 3, 1943, judgment of condemnation was entered ordering that the article be destroyed; and on October 1, 1943, the motion for a new trial, which had been filed by the intervenor was denied.

1381. Misbranding of Azmarin Tablets. U. S. v. 140 Packages of Azmarin Tablets. Default decree of condemnation and destruction. (F. D. C. No. 12322. Sample No. 60334–F.)

On May 10, 1944, the United States attorney for the Northern District of California filed a libel against 140 packages of Azmarin Tablets at San Francisco, Calif., alleging that the article had been shipped on or about April 5, 1944, by the Azmarin Co., from Miami, Fla.

Examination showed that the article consisted essentially of aspirin, 4.4 grains per tablet, with small proportions of sulfur, potassium bitartrate, and plant material.

The article was alleged to be misbranded because of false and misleading statements on the box label and in the accompanying leaflets entitled "Azmarin Tablets and Method of Treatment in Colds & Coughs," and "What Every Sufferer From Colds, Catarrh, Hay Fever, Sinus, Bronchitis and Asthma Should Know," regarding its efficacy in the prevention or treatment of colds, coughs, excess mucus conditions, catarrh, hay fever, sinus trouble, bronchitis, asthma, influenza, bad conditions of the blood, spasm, acid conditions, irritated or inflamed mucous membrane, nervousness, difficult breathing, and choking and smothering spells. It was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient, since aspirin had been designated on the label as acid acetylsalicylic.

On September 14, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1382. Misbranding of DPS Formulae 80, 81, and 200. U. S. v. 11 Bottles of DPS Formula 80, 7 Bottles of DPS Formula 81, 14 Bottles of DPS Formula 200, and a quantity of printed matter. Default decree of condemnation and destruction. (F. D. C. No. 12354. Sample Nos. 54123–F, 54177–F, 54178–F.)

On or about May 19, 1944, the United States attorney for the District of Arizona filed a libel against 11 4-ounce bottles of Formula 80, 7 100-tablet bottles of Formula 81, 14 90-tablet bottles of Formula 200, and a quantity of printed matter at Phoenix, Ariz., alleging that the articles and the printed matter had been shipped on or about February 29 and March 15, 1944, by the Dartell Laboratories, Los Angeles, Calif. The printed matter consisted of 12 index cards entitled "DPS Series 80," 12 folders entitled "DPS Series 80 * * * Improved Method For The Use of Chlorophyll In The Treatment of Disease," 25 circulars entitled "Amino Acid Formula Victory Over Achlorhydria And Sequelae," and a booklet entitled "DPS Dartell Formulae."

Examination disclosed that the Formula 80 consisted of an aqueous solution of sodium chloride and a compound of chlorophyll; that the Formula 81 consisted essentially of a soluble chlorophyll derivative incorporated in tablet