

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess.

It was also misbranded in that the statements with respect to the mineral content were false and misleading, since the statements were incorrect. It was further misbranded since statements made in the labeling representing and suggesting that the product was efficacious as a dietary supplement, as a body builder, as a tonic, and to correct disorders arising from dietary deficiencies, were false and misleading. The product was also recommended in the labeling as efficacious in the treatment of arthritis, rheumatism, neuritis, influenza, and phlebitis, and was represented as a combination of inorganic minerals in their most assimilable form, which would supply the minerals necessary to normal nutrition in the most desirable amounts. In fact, the article was not efficacious for the purposes recommended and was not a combination of inorganic minerals in their most assimilable form, which would supply the minerals necessary to normal nutrition in the most desirable amounts.

On October 9, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

926. Adulteration of Mennen Antiseptic Oil. U. S. v. 38 Packages of Mennen Antiseptic Oil. Default decree of condemnation. Product ordered delivered to New York City Salvage Committee. (F. D. C. No. 8250. Sample No. 16841-F.)

On August 27, 1942, the United States attorney for the Southern District of New York filed a libel against 38 packages of Mennen Antiseptic Oil at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about February 16, 1942, by the Mennen Co., from Newark, N. J.

Bacteriological examination showed that the article was neither germicidal nor self-sterilizing. Chemical examination showed that it consisted of a yellow, perfumed, saponifiable oil containing small amounts of hydroxyquinoline, chlorobutanol, hydroquinone, and benzoic acid. The article was alleged to be adulterated in that its strength differed from that which it was represented to possess in the labeling, "Germicidal * * * Self Sterilizing."

It was alleged to be misbranded in that the following statements appearing in the labeling were false and misleading since the article was not a germicide, was not self-sterilizing, and was not efficacious for the symptoms and conditions mentioned: "* * * Germicidal * * * Self-Sterilizing * * * It is so medicated as to make the oil * * * germicidal * * * self-sterilizing. * * * It has equal antiseptic and germicidal powers to the commonly used ammoniated mercury ointments. * * * The oil is self-sterilizing, and autoclaving is not necessary. * * * It helps kill and prevent the growth of pyogenic organisms as long as it is in contact with the skin. * * * It helps maintain and conserve vital body temperature. It helps sterilize * * * the diaper area. * * * Meets the widespread demand of hospitals, physicians, nurses and mothers * * * germicidal * * * and self-sterilizing oil * * * offers protection against infection * * * Mennen Antiseptic Oil aids in keeping the skin of the babies free from pyogenic organisms. * * * quickly relieves * * * aggravated skin conditions. Prescribed where * * * germicidal oil dressing is required."

It was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label failed to bear a statement of the quantity or proportion of chlorobutanol, a chloroform derivative, contained therein.

On October 1, 1942, no claimant having appeared, judgment of condemnation was entered and the court ordered the marshal to deliver the article to the New York City Salvage Committee for national defense and salvage purposes.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS²²

DRUGS FOR HUMAN USE

927. Action to restrain and enjoin interstate shipment of Dolphin's Natural Barks. U. S. v. Byron J. Dolphin (Dolphin's Natural Barks). Tried to the court and jury. Verdict in favor of the Government. Permanent injunction granted. (Inj. No. 44.)

On December 5, 1942, the United States attorney for the Western District of Washington filed a complaint against Byron J. Dolphin, doing business as Dolphin's Natural Barks at Seattle, Wash., alleging that the defendant for many years past had been engaged in the sale and distribution of an article of drug

²² See also Nos. 901-903, incl., 905-914, incl., 917-922, incl., 924-926, incl.

called Dolphin's Natural Barks, and that the article was made up in liquid form and sold and distributed by the defendant in small glass bottles enclosed in cardboard cartons.

The complaint alleged further that the article was misbranded in that certain statements appearing in its labeling were false and misleading. (The misbranding allegations in the complaint were sustained by the court's "Findings of Fact" and "Conclusions of Law" set forth hereinafter.)

The complaint alleged further that the defendant and his agents had been in the past and were then introducing and delivering the article for introduction into interstate commerce, and prayed that judgment and decree be entered permanently restraining and enjoining the defendant, his agents and employees, and all persons acting in concert with them, from continuing to do so, and prayed that a preliminary injunction be granted restraining the defendant during the pendency of the action. On the same date and pursuant to the motion of the United States attorney, an order was entered for the defendant to show cause why he, his agents, and employees should not be restrained and enjoined during the pendency of the action.

On December 14, 1942, the case having come on for hearing, the court orally ruled that the Government was entitled to the preliminary injunction on the ground that its evidence, showing the article had no curative value, was uncontroverted, and on December 16, 1942, a restraining order pendente lite was entered pursuant to such oral ruling.

The case came on for trial on March 7, 1944, at which time the court, upon its own motion impaneled an advisory jury. On March 9, 1944, evidence having been admitted on behalf of the parties and the cause submitted to such jury, a verdict was returned in favor of the Government, together with a special verdict finding that the product was misbranded. On March 20, 1944, the court having duly considered the matter, made the following findings of fact and conclusions of law:

BOWEN, District Judge:

FINDINGS OF FACT

I.

"That the defendant BYRON J. DOLPHIN is a resident of Seattle, Washington, and is doing business under the firm and trade name of Dolphin's Natural Barks.

II.

"That the defendant has been for some years past and is now engaged in the manufacture, sale and distribution of a product and article of drug called 'Dolphin's Natural Barks,' and that said product is made up in liquid form and is sold and distributed by the defendant in small glass bottles enclosed in cardboard cartons.

III.

"That there is attached and affixed to the said cartons and to the said bottles certain labels, and there is inserted in each carton a leaflet or circular, and that such labels and leaflet make certain statements and representations concerning said product, its constituents and the efficacy of said product as a treatment for diseases of the eye; that the leaflet contained in said carton constitutes a part of the labeling of said product.

IV.

"That the statements and representations appearing on the said labeling regarding the efficacy of said product in the cure, mitigation, treatment or prevention of diseases of the eye are false and misleading in that they falsely represent and suggest: That said drug contains natural barks; that drops of said drug when applied to the eyes are wonderful for diseases of the eye; that said drug is manufactured by a new process from tamarack bark, oak bark, and contains minerals from organic and inorganic sources, to-wit, aluminum, iron, manganese, calcium, magnesium, sodium and potassium; that the continued use of said drug will remove the sting from eyes which are in bad condition because of disease; that said drug will restore eyesight and prevent blindness; that said drug is efficacious and beneficial in the cure, mitigation, treatment and prevention of granulated eyelids and ulcers; that said drug has been efficacious and beneficial in the cure, mitigation, treatment and prevention of disease of the eye after

doctors have failed to give relief; that said drug is a miraculous and mysterious discovery revealed by Divine Providence.

V.

"That said drug does not constitute an appropriate or effective remedy for the purposes stated, recommended and suggested in said labeling; that said product and drug does not contain the ingredients it is represented to contain in said labeling; that the said product is essentially water.

VI.

"That the defendant has heretofore shipped the said product and drug with the aforesaid labeling accompanying it in interstate commerce from Seattle, Washington, to various parts of the United States.

"From the foregoing FINDINGS OF FACT, the Court makes the following:

CONCLUSIONS OF LAW

I.

"That the Court has jurisdiction of the parties to this action and of the subject matter thereof.

II.

"That the product 'Dolphin's Natural Barks' is a drug within the meaning and contemplation of the Federal Food, Drug and Cosmetic Act.

III.

"That the printed matter affixed to the bottle which contains said drug and to the carton in which said drug is packaged, and to the leaflet or circular inserted in said carton constitutes and is the labeling of said product within the meaning and contemplation of the Federal Food, Drug and Cosmetic Act.

IV.

"That the said product and drug 'Dolphin's Natural Barks' is misbranded within the meaning and contemplation of the Federal Food, Drug and Cosmetic Act.

V.

"That the defendant has heretofore violated the provisions of the Federal Food, Drug and Cosmetic Act, and that said defendant, his agents and employees and any and all persons acting in concert with said defendant or his agents or employees should be permanently restrained and enjoined from introducing or delivering for introduction in interstate commerce, or from in any manner aiding or assisting in the introduction or delivery for introduction into interstate commerce of the said product and drug 'Dolphin's Natural Barks.'

VI.

"That the plaintiff should recover judgment against the defendant for its costs herein incurred."

On the same date, March 20, 1944, a decree was entered granting a permanent injunction in accordance with the prayer of the complaint.

928. Alleged misbranding of Dolphin's Natural Barks. U. S. v. Byron J. Dolphin (Dolphin's Natural Barks). Plea of not guilty. Tried to a jury. Verdict of guilty. Motion for new trial granted and case subsequently dismissed. (F. D. C. No. 7243. Sample No. 11343-E.)

On July 16, 1942, the United States attorney for the Western District of Washington filed an information against Byron J. Dolphin, trading as Dolphin's Natural Barks, Seattle, Wash., alleging shipment on or about December 27, 1941, from the State of Washington into the State of Texas of a quantity of a drug, known as Dolphin's Natural Barks, which was misbranded.

Analysis of a sample of the article showed that it consisted essentially of water containing 0.0060 gram of solids per 100 cc.

It was alleged to be misbranded in that certain statements in its labeling which represented and suggested that it contained natural barks; that drops of the article, when applied to the eye, were wonderful for diseases of the eye; that it was manufactured by a new process from tamarack bark and oak bark,