

creasing sexual potency, checking the appetite, bringing about a loss of body weight, soothing the stomach, relieving coughs, and the pain of arthritis and nervousness, treating hay fever, healing burns, preventing fatigue and aiding digestion.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-2-59. Consent—claimed by L. C. Antles and relabeled.

5806. Trifosan tablets. (F.D.C. No. 42289. S. No. 28-362 P.)

QUANTITY: 1 bulk drum, containing 50,000 tablets, and 102 btl. of tablets, at Birmingham, Ala., in possession of Veltex Co.

SHIPPED: 3-5-57, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Trisfosan Tablets * * * An Herbal Compound with Potassium Iodide especially adapted as an aid in helping to reestablish nutritive processes. * * * Each Tablet Contains: Powd. Ext. Trifolium 1 grain, Powd. Ext. Stillingia Root $\frac{1}{4}$ grain Potassium Iodide $\frac{1}{2}$ grain Powd. Ext. Lappa $\frac{1}{2}$ grain Powd. Ext. Phytolacca $\frac{1}{2}$ grain Powd. Ext. Berberis Aquifolium $\frac{1}{2}$ grain Powd. Ext. Xanthoxylum $\frac{1}{8}$ grain Powd. Ext. Echinacea Root $\frac{1}{4}$ grain Powd. Ext. Sarsaparilla Root $\frac{1}{8}$ grain With Oil anise and Powd. Ext. Licorice Root as flavors * * * Take one tablet three times daily * * * The Veltex Company Distributors—Birmingham, Alabama."

ACCOMPANYING LABELING: Pamphlet designated "Catalogue No. 106-CN * * * Veltex Company Manufacturing Chemists."

RESULTS OF INVESTIGATION: The bottle of tablets were repacked and labeled by the Veltex Co. from the tablets contained in the bulk drum described above.

LIBELED: 11-7-58, N. Dist. Ala.

CHARGE: 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was effective for overcoming digestive and nutritive disturbances, boils, and "poor blood."

DISPOSITION: 11-25-58. Consent—claimed by the Veltex Co. and relabeled.

5807. Lotion-Jel. (F.D.C. No. 42055. S. No. 14-827 P.)

QUANTITY: 336 tubes at Indianapolis, Ind.

SHIPPED: 5-15-58, from Cincinnati, Ohio, by Grandpa Soap Co.

LABEL IN PART: "Dent's Lotion-Jel * * * C. S. Dent, Cincinnati 2, O."

RESULTS OF INVESTIGATION: Examination showed that the article contained 4.75 percent benzocaine (Ethyl Aminobenzoate) in a jel-type base.

LIBELED: 8-12-58, S. Dist. Ind.

CHARGE: 502(a)—the label of the article and a display card accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for any gum discomfort, gum soreness, gum boils, denture irritations, and similar irritations of the gums.

DISPOSITION: 1-26-59. Default—destruction.

5808. Buticaps capsules. (F.D.C. No. 38723. S. Nos. 20-060/1 M.)

QUANTITY: 204 pkgs. at Washington, D.C.

SHIPPED: 9-8-55, from Los Angeles, Calif., by Buticaps, Inc.

LABEL IN PART: (Pkg.) "Buticaps the internal skin conditioner For Normal or Dry Skin 30 Capsules * * * A dietary supplement recommended as an aid

in skin conditioning containing the multiple vitamin group, certain Lipotropic agents and Vitamins H, H-1 and (F)—for the treatment of a deficiency of one or more of the following ingredients: Each capsule contains: Vitamin A Palmitate 25,000 USP Units Free Fatty Acids of Linseed Oil 20 Milligrams Principally Linoleic and Linolenic Acids, (Vitamin F) Choline Bitartrate 40 Milligrams Inositol 20 Milligrams dl-Methionine 15 Milligrams Betaine Monohydrate 10 Milligrams Vitamin B-12 USP (Crystalline) 2 Micrograms Folic Acid 100% USP 0.5 Milligram Thiamine Mononitrate 10 Milligrams Pyridoxine Hydrochloride 1 Milligram Riboflavin 6 Milligrams Niacinamide 20 Milligrams Vitamin D (Irradiated Ergosterol) 500 USP Units Calcium Pantothenate 20 Milligrams Ascorbic Acid 50 Milligrams Biotin (Vitamin H) 0.12 Milligram Para-amino Benzoic Acid 5 Milligrams (Bacterial Vitamin H-1) Mixed Tocopherols 5 Milligrams Plus Vitellin (Lecithin from Soya Bean) 25 Milligrams" and (pkg.) "Buticaps the internal skin conditioner For Oily Skin 30 Capsules * * * A dietary supplement recommended as an aid in skin conditioning containing the multiple vitamin group, certain Lipotropic agents and Vitamins H, H-1 and (F)—for the treatment of a deficiency of one or more of the following ingredients: Each capsule contains: Pyridoxine Hydrochloride 5 Milligrams Free Fatty Acids of Linseed Oil 10 Milligrams Principally Linoleic and Linolenic Acids, (Vitamin F) Choline Bitartrate 40 Milligrams Inositol 40 Milligrams dl-Methionine 30 Milligrams Betaine Monohydrate 10 Milligrams Vitamin B-12 USP (Crystalline) 2 Micrograms Folic Acid 100% USP 0.5 Milligram Thiamine Mononitrate 10 Milligrams Vitamin A—Palmitate 15,000 USP Units Riboflavin 6 Milligrams Niacinamide 20 Milligrams Vitamin D (Irradiated Ergosterol) 500 USP Units Calcium Pantothenate 20 Milligrams Ascorbic Acid 50 Milligrams Biotin (Vitamin H) 0.16 Milligram Para-amino Benzoic Acid 5 Milligrams (Bacterial Vitamin H-1) Mixed Tocopherols 5 Milligrams Plus Vitellin (Lecithin from Soya Bean) 25 Milligrams."

ACCOMPANYING LABELING: Booklet entitled "here's how * to promote * to sell * to profit with Buticaps" and leaflets entitled "Buticaps."

LIBELED: 11-30-55, Dist. Columbia; libel amended, 9-17-56.

CHARGE: 502(a), when shipped,

(1) the labeling contained false and misleading representations that the article was an adequate and effective treatment for dry or oily skin, unsightly blemishes of acne and other skin disorders in the adolescent, and skin conditions due to overindulgence; was a revolutionary new approach to skin conditioning; would aid in prematurely "aged skin"; was effective in retaining the normal moisture and stabilizing the oil balance of the skin; had beneficial effects on the eyes, hair, scalp, teeth and gums; would bring nourishment to a starving complexion and aid in carrying away wastes which cause unsightliness; and was an effective treatment for scaly or cracked skin, enlarged pores, unnecessary wrinkles and that tired look;

(2) the designations "Vitamins, H, H-1 and (F)" appearing on the package labels were false and misleading since use of such designations were obsolete and no longer had any recognized use and implied promise of benefit from vitamins with which the user was not familiar;

(3) the label designation "Plus Vitellin (Lecithin from Soya Bean)" was false and misleading since "Vitellin" is not lecithin from soy beans but is the common or usual name for a protein prepared from yolk of eggs; and

(4) the name "*Buticaps*" was false and misleading since it represented, suggested, and implied that the article would beautify the skin of the user whereas it would not beautify the skin of the user.

DISPOSITION: Buticaps, Inc., Los Angeles, Calif., appeared as claimant and admitted the material allegations in the libel except the claimant denied that the name "*Buticaps*" was false and misleading.

Thereafter, the Government filed a motion for judgment on the pleadings on the ground that all material facts had been admitted by the answer. On 1-25-57, the district court granted the Government's motion and ordered that the article be released for relabeling under the supervision of the Department of Health, Education, and Welfare. On 2-28-57, the claimant filed a motion to relabel and requested the court to specify that there had been no judicial determination that the name "*Buticaps*" did not comply with the statute and that the name need not be changed. The claimant's motion was denied by the court on 4-8-57.

Thereafter, on 5-21-57, the court having determined that because of the claimant's insistence upon the use of the name "*Buticaps*," further efforts to relabel would be fruitless, the article was ordered destroyed. The claimant then appealed to the United States Court of Appeals for the District of Columbia which reversed the decision of the trial court in the following opinion on 1-30-58 (252 F. 2d 634) :

PER CURIAM: "The libel in this case was filed to condemn certain articles of drug (a claimed skin conditioner) in accordance with the Federal Food, Drug and Cosmetic Act.¹ It was claimed that the articles were misbranded within the meaning of said Act in that: (1) as alleged in paragraph 3 of the libel a leaflet entitled 'Buticaps' enclosed in each package, and a booklet entitled 'here's how * to promote * to sell * to profit with Buticaps' contained statements which were false and misleading; and (2) as alleged in paragraph 4 of the libel the aforementioned articles were further misbranded in that the designations of certain vitamins and proteins appearing on the package labels were false and misleading.

"Thereafter, the libel was amended by adding paragraph 3(a) to allege that the name 'Buticaps' on the package labels, leaflet and booklet represents and implies that the articles will beautify the skin of the user, which is false and misleading since the articles will not beautify the skin of the user.

"After answer by libelee admitting the allegations in paragraphs 3 and 4 of the libel but denying the allegations in paragraph 3(a) as to the use of the word 'Buticaps,'² the Government filed motion for judgment on the pleadings. This motion was not opposed but, in the answer thereto, libelee [claimant] urged: 'If this Motion is granted, claimant's pleading with regard to the name "Buticaps" must be taken as true.'

"The District Court filed a memorandum announcing that it would grant the motion for judgment on the pleadings but would exercise its discretion in not ordering the articles destroyed, as it had a right to do,³ and would release the seized articles for relabeling. The court's memorandum contained the following language:

* * * Provided, however, that the claimant post a good and sufficient bond to insure compliance with the statute and that relabeling is done under the supervision of an officer or employee duly designated by the Secretary of the Department of Health, Education and Welfare, as the statute provides, the expenses of such supervision to be paid by the claimant. The Court regards these provisions as mandatory.

Order accordingly.

¹ 21 U.S.C.A. § 301-392 (1952)

² It was claimed by libelee in its answer that the name was "neither false nor misleading since it is a coined word which has no meaning aside from the meaning given it by naming this product."

³ 21 U.S.C.A. § 334(d)

"Thereupon, on February 19, 1957, the court ordered that judgment on the pleadings be entered in favor of plaintiff [libelant].

"On February 28, 1957, libelee moved the court for an order directing that the condemned articles be delivered to libelee and requesting that the court specify, pursuant to the judgment on the pleadings, that the statute was found to have been violated in the following manner and only in the following manner:

"(1) Misbranding in reference to a leaflet entitled 'Buticaps,' enclosed in each package of the condemned article;

"(2) Misbranding in reference to two designations appearing on the label of the seized articles.

"Libelee asked that the court 'further specify that the seized articles must now be brought into compliance with the Federal Food, Drug and Cosmetic Act * * * by appropriate relabeling but that, pursuant to the aforesaid judgment, there has been no judicial determination in this action that the name "Buticaps" does not comply with the statute, which name need, therefore, not be changed under the judgment entered heretofore in this action.'

"The Government's reply to the motion stated that the position of the *Department of Health, Education and Welfare* was that the name 'Buticaps' is false and misleading, and that it would be a violation of the statute to allow relabeling under that name. Thereupon, on May 21, 1957, the court entered its order reciting, among other things, that because of libelee's insistence upon the use of the name 'Buticaps,' further efforts to relabel would be fruitless; and the court directed that the articles seized be destroyed by the United States Marshal. This appeal followed:

"We think this ruling of the District Court was erroneous. The judgment on the pleadings was limited, of necessity, to the admitted facts. We believe that the refusal of the Department of Health, Education and Welfare to allow relabeling unless the word 'Buticaps' was eliminated was unauthorized, and that libelee was entitled to a *judicial* hearing and ruling on the question of the alleged misuse of the word. See *Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 70 S. Ct. 870, 94 L. Ed. 1088 (1950).

"We agree that as the Government contends, '[b]y violating the law and introducing a misbranded drug into interstate commerce, the owner of the article, after there has been a judicial determination that the article violates the law, loses any *right* to repossess his property' and that '[h]e regains the property upon such terms and conditions as to the trial court seem just and proper, within the confines of the powers conferred by Section 304(d) of the Act' [21 U.S.C.A. § 334(d)]. But the terms and conditions are to be fixed by the *court* and not by the Department of Health, Education and Welfare. Libelee is entitled to judicial due process.

"It is no answer, as urged by libelant, to say that the name 'Buticaps' itself implies that the article will impart beauty. It may be that, on hearing, the court, on evidence, could determine that the use of the name 'Buticaps' is misleading. As to this, we express no opinion.

"Accordingly, the judgment of the District Court is reversed; and the case is remanded to that court, either to proceed to the judgment of relabeling, insofar as the admitted violations are concerned, or, if the court be so advised, to re-open the case to determine the issue as to the use of the word 'Buticaps.'⁴

"Reversed and remanded."

Thereafter, on 6-4-58, the claimant filed a motion for judgment of relabeling. On 6-6-58, the trial court vacated its order of 5-21-57, and ordered that the cause proceed to judgment of relabeling as to admitted violations, or if the court be so advised, that it be reopened to determine the issue as to the use of the word "*Buticaps*." On the same day, the Government filed such a motion to reopen, and the Government's motion to reopen was granted on 10-24-58 and claimant's motion to relabel was denied.

⁴ It is noted that libelant, at the hearing on the motion of libelee to relabel the condemned articles, orally moved that the case be reopened for the purpose of trial on "the merits of that one issue."

On 1-6-59, the claimant asserting that it was financially unable to prosecute further its claim to the article, and the claimant having discontinued the manufacture of the article known as "*Buticaps*," it was stipulated and agreed between the Government and the claimant that the claimant's claim be withdrawn and that the article under seizure be destroyed, and accordingly the article was ordered condemned and destroyed on 1-22-59.

5809. Sugar-chek (urine sugar test tape) (2 seizure actions). (F.D.C. No. 42177, 42178. S. Nos. 14-647/8 P.)

QUANTITY: 426 display ctns., each ctn. containing 36 envelopes, and each envelope containing 1 piece of treated tape (paper) in a sealed package and 1 leaflet, at Chicago and Forest Park, Ill.

SHIPPED: During 1957, from St. Louis, Mo., to Springfield, Ill., from where it was re-shipped to Chicago and Forest Park, Ill.

LABEL IN PART: (Envelope) "Sugar-Chek."

ACCOMPANYING LABELING: Leaflet entitled "What is a Diabetic?"

LIBELED: 9-8-58, N. Dist. Ill.

CHARGE: 502(a)—while held for sale; the labeling of the article contained false and misleading representations that the article was effective for detecting the presence of sugar in the urine, and thus acting as a diagnostic sign of diabetes.

DISPOSITION: 10-30-58 and 10-31-58. Default—destruction.

5810. Magic copper band. (F.D.C. No. 42287. S. No. 21-678 P.)

QUANTITY: 749 devices, each in a plastic box, at Lincoln, Nebr., in possession of M. J. Co.

SHIPPED: 3-18-58, from Providence, R.I.

LABEL IN PART: (Label insert in box) "Here is Your Magic Copper Band"; (back of label) "Handy Order Form Mail to: Magic Copper Band * * * Lincoln, Nebr."

RESULTS OF INVESTIGATION: Examination showed that the article was a copper-colored metal band $\frac{1}{4}$ inch in width, and, when open, about 6 inches in length.

The above-described label inserts were printed locally for the dealer.

LIBELED: 11-13-58, Dist. Nebr.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relief from the pains of arthritis and rheumatism.

DISPOSITION: 12-17-58: Default—destruction.

5811. Exercycle devices. (F.D.C. No. 40644. S. No. 68-225/6 M.)

QUANTITY: 24 devices at Kansas City, Mo.

SHIPPED: Between 6-17-57 and 8-26-57, from Hartford, Conn., by the Exercycle Corp.

ACCOMPANYING LABELING: Leaflets designated "Feeling Like A Million" and a pamphlet entitled "Organizational Bulletin No. 119."

RESULTS OF INVESTIGATION: The device consisted of a framework resembling a wheelless bicycle equipped with an electric motor which produced motion of the pedals, seat, and handlebars.

LIBELED: 9-19-57, W. Dist. Mo.