3798. Misbranding of MacLevy hand massagers. U. S. v. 10 Devices, etc. (F. D. C. No. 32220. Sample No. 32371–L.)

LIBEL FILED: December 6, 1951, Eastern District of Arkansas.

ALLEGED SHIPMENT: On or about August 21, 1951, by the MacLevy Equipment Corp., from New York, N. Y.

PRODUCT: 10 *MacLevy hand massagers* and 9 leaflets entitled "Reduce At Home" at Pine Bluff, Ark. The device consisted of 4 rubber balls mounted on a metal shaft with a handle at each end.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying leaflets entitled "Reduce At Home" were false and misleading since they represented and suggested that the device would be effective to bring about a reduction in weight, whereas the device would not be effective for that purpose.

DISPOSITION: January 24, 1952. Default decree of condemnation. The court ordered that the 5 devices which actually were seized under the libel and the leaflets be delivered to the Food and Drug Administration for exhibit purposes.

3799. Misbranding of Therm-Massage infrared heat applicator. U. S. v. 2,000 Cartons, etc. (F. D. C. No. 32221. Sample No. 3702–L.)

LIBEL FILED: On or about December 4, 1951, District of Maryland.

ALLEGED SHIPMENT: On or about October 25 and 26, 1951, from Newark, N. J.

PRODUCT: 2,000 *Therm-Massage infrared heat applicators* in individual cartons at Baltimore, Md., together with a number of cards headed "Infra-Red Therm-Massage Heat Applicator." The cards were printed locally.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the above-mentioned cards accompanying the device were false and misleading since the device was not an adequate and effective treatment for the conditions stated and implied and was not capable of fulfilling the promises of benefit made for it: "Infra-Red Therm-Massage Heat Applicator * * * Indicated for * * * aching joints, backache, rheumatism, aching muscles, foot cramps, arthritis, stiff neck, sinus, neuritis * * * sprains * * * leg cramps * * * Is your Family Protected Right Now? * * * Notice how quickly sore muscles begin to relax, aching nerves and joints feel better * * * Pain may come suddenly. Here's quick convenient inexpensive relief * * * Say No, to aches and pains * * * Arthritis Relief * * * have had arthritis for many years and this * * * has * * * given me relief * * * (pictures with legends 'Back Pains! Foot Pains! Sprains, bruises, foot and leg cramps. Head Pains! Soothing Infra-Red Heat and Massage for colds, headache, sinus')." The device was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 8, 1952. National Health Aids of Baltimore, Inc., Baltimore, Md., having appeared as claimant and filed an answer to the libel, and later having withdrawn its answer, judgment of condemnation was entered and the court ordered that the devices be destroyed. On September 10, 1952. an order was entered providing for the delivery of three of the devices and their labeling to the Food and Drug Administration.

3800. Misbranding of Le Joi devices. U. S. v. 822 Devices, etc. (F. D. C. No. 33197. Sample No. 17207–L.)

LIBEL FILED: April 24, 1952, Southern District of California; amended libel filed April 24, 1952.

ALLEGED SHIPMENT: On or about February 21 and March 3, 12, 14, 18, and 24, 1952, from Minneapolis, Minn.

PRODUCT: 822 *Le Joi devices* at Los Angeles, Calif., in possession of Pro-Tex, Inc., together with accompanying leaflets entitled "Instructions Le Joi" and "New Horizons." The latter leaflet had been printed locally for the above corporation. Examination showed that the device consisted of a thin rubber tube with a locking attachment at each end.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying leaflets "New Horizons" were false and misleading. The statements represented and suggested that use of the device was effective in improving the sexual capacities of older men by enlarging and reinforcing the sexual organ. The device was not effective for such purposes, and it would not fulfill the promises of benefit made for it. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: August 13, 1952. Vita Pharmacals, Inc., Los Angeles, Calif., having filed its claim and answer to the libel and subsequently having withdrawn such claim and answer, judgment of condemnation was entered and the court ordered that the 2 devices which actually were seized under the libel be delivered to the Food and Drug Administration.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3781 TO 3800

PRODUCTS

	N. J. No.
Adhesive bandages	3791
Alcoholism, remedy for	3796
Amphetamine sulfate tablets	3782
dextro-, sulfate tablets	3782, 3792
Arthritis, remedies. *See* Rheumatism, remedies for.	
Bandages, adhesive	3791
Cortisone acetate tablets	[1] 3785
Devices	3797–3800
Dextro-amphetamine sulfate tablets	3782, 3792
Diethylstilbestrol tablets	3782
Diuretic	3795
Ebrey Extract	3795
Epinephrine hydrochloride injection	3787
Erbacidin tablets	3781
Estrogenic substance	3782
Gall bladder, treatment for	3784
Grindelia	3788
Herb preparations	3784
High blood pressure remedy	3784
In-Flam-Go	3794
Infrared heat applicator, Therm-Massage	3799
Inorganic Nutrient tablets	3793
Iron tonic, Mer-I-Col	3783
Laxative without required warning statements	3784
Lecithin, soya	3793
Le Joi devices	3800
MacLevy hand massagers	3798
Massagers, hand, MacLevy	3798
Mer-I-Col iron tonic	3783
Nutrient tablets	3793
Old Chief's prostate treatment, Old Chief's nerve special, Old Chief's Indian gall bladder herb tea, Old Chief's Indian high blood pressure herb tea, Old Chief's Indian reducing obesity herbs, and Old Chief's Indian laxative herb tea	3784
Pentobarbital sodium capsules	3786
Phenacetin tablets	3786
Phenobarbital tablets and phenobarbital and atropine sulfate tablets	3786
Prostate treatment	3784

[1] (3785) Prosecution contested. Contains opinions of the court.

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3801–3820

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *February 10, 1953.*

CONTENTS*

	Page
Drugs actionable because of failure to bear adequate directions or warning statements	296
Drugs and devices actionable because of deviation from official or own standards	298
Drugs and devices actionable because of false and misleading claims	301
Drugs for human use	301
Drugs and devices actionable because of false and misleading claims—Continued.	
Drugs for veterinary use	305
Drug actionable because of failure to bear a label containing an accurate statement of the quantity of the contents	307
Index	308

*For presence of a habit-forming narcotic without warning statement, see Nos. 3802, 3803; omission of, or unsatisfactory, ingredients statements, Nos. 3801–3803, 3814, 3815; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3801, 3802.

237174—53——1

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3801. Adulteration and misbranding of dextro-amphetamine sulfate tablets and amphetamine sulfate tablets. U. S. v. 232,000 Tablets, etc. Tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 31408. Sample Nos. 20953–L, 20987–L, 20988–L.)

LIBEL FILED: On or about August 3, 1951, Northern District of Texas; amended on or about September 21, 1951.

ALLEGED SHIPMENT: On or about January 29, 1951, by the Kumfort Drug Products Co., from Cleveland, Ohio.

PRODUCT: 232,000 *dextro-amphetamine sulfate tablets* and 15,000 *amphetamine sulfate tablets* in labeled and unlabeled bottles at Dallas, Tex., in possession of Ward's Cut Rate Drugs.

Analysis showed that the 232,000-tablet lot contained 5 mg. of a mixture of racemic and dextro-amphetamine sulfate per tablet and that the 15,000-tablet lot contained 6.5 mg. of amphetamine sulfate per tablet.

RESULTS OF INVESTIGATION: The articles were shipped in unlabeled bottles, and portions of both articles were labeled by the consignee.

NATURE OF CHARGE: Adulteration, Section 501 (d), (232,000-tablet lot) a substance, namely, tablets each containing 5 mg. of a mixture of racemic and dextro-amphetamine sulfate, had been substituted for 5 mg. *dextro-amphetamine sulfate tablets*, and (15,000-tablet lot) a substance, namely, 6.5 mg. amphetamine sulfate tablets, had been substituted for 10 mg. *amphetamine sulfate tablets*. Misbranding, Sections 502 (b) (1) and (2), (unlabeled bottles) the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Sections 502 (f) (1) and (2), the labeling of the articles failed to bear adequate directions for use and such adequate warnings against use where their use may be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form, as are necessary for the protection of users. The articles were adulterated and misbranded in these respects when introduced into, while in, and while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (e) (2), (232,000-tablet lot) the label of the article failed to bear the common or usual name of each active ingredient. The article was misbranded in this respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the label designations, namely, (232,000-tablet lot) "Dextro Amphetamine Sulfate 5 Mg." and (15,000-tablet lot) "Racemic Amphetamine Sulfate 10 Mg.," were false and misleading as applied to articles containing, respectively, 5 mg. of a mixture of racemic and dextro-amphetamine sulfate per tablet and 6.5 mg. of amphetamine sulfate per tablet. The articles were misbranded in these respects while held for sale after shipment in interstate commerce.

DISPOSITION: Ward's Cut Rate Drugs having appeared as interveners, the case came on for trial before the court without a jury, on September 24, 1951. At the conclusion of the trial, the court found that the law and the facts were with the Government, and on September 26, 1951, a decree of condemnation and destruction was entered.