

Further misbranding, Section 502(f) (2), (2 shipments) the labeling failed to bear adequate warnings against use in those pathological conditions where the use of the article may be dangerous to health, and against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users since each tablet contained 10 milligrams of methyl testosterone; and the labeling of the article failed to bear adequate warnings against use by individuals who may have cancer of the prostate since the ordinary lay user is not familiar with the indications of cancer of the prostate.

*Alpha estradiol tablets.* Misbranding, Section 502(a), certain statements in the labeling, i. e., in the accompanying circular entitled "The Male Hormone," were false and misleading. The labeling represented and suggested that the article would relieve and postpone the many conditions associated with middle age, and that the article constituted an adequate treatment for hot flashes, emotional disturbances and other manifestations associated with the menopause. The article would not be effective for such purposes.

DISPOSITION: March 24, 1950. A plea of guilty having been entered, the court fined the defendant \$800, plus costs.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

3209. Adulteration and misbranding of adhesive bandages. U. S. v. 180 Cartons, etc. (and 2 other seizure actions). (F. D. C. Nos. 28995, 29235, 29272. Sample Nos. 46598-K, 46599-K, 47244-K, 47245-K, 47547-K.)

LIBELS FILED: April 25, May 19, and June 14, 1950, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 2, April 17, and May 1, 1950, by the Seamless Rubber Co., from New Haven, Conn.

PRODUCT: Adhesive bandages. 540 cartons, each containing 12 tins, 23 boxes, each containing 720 tins, and 780 cartons, each containing 12 tins, at Pittsburgh, Pa.

LABEL IN PART: "Quik-Bands Assorted Sterilized Plain [or "Quik-Bands Assorted with Mercurochrome \* \* \* Sterilized"] \* \* \* Adhesive Bandages" and "Rexall First Aid Quik-Bands Adhesive Bandages."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (a), the label statements "Sterile," "First Aid," and "Sterilized" were false and misleading as applied to an article that was not sterile.

DISPOSITION: July 21 and August 4, 1950. The Seamless Rubber Co. having appeared as claimant for the lot of 540 cartons and the lot of 23 boxes and consented to the entry of decrees, judgments of condemnation were entered and the court ordered that such lots be released under bond to be brought into compliance with the law by reesterilization. In the matter of the lot of 780 cartons, only 60 cartons were on hand at the time of seizure. No claimant

\*See also No. 3201.

having appeared for the 60 cartons, the court entered a default decree of condemnation and destruction.

**3210. Adulteration and misbranding of prophylactics. U. S. v. 63 Cartons \* \* \*. (F. D. C. No. 28994. Sample No. 50851-K.)**

**LIBEL FILED:** April 28, 1950, Western District of Washington.

**ALLEGED SHIPMENT:** On or about March 23, 1950, by the Dean Rubber Mfg. Co., from North Kansas City, Mo.

**PRODUCT:** 63 cartons, each containing 12 packages, of *prophylactics* at Seattle, Wash. Examination of samples showed that 5.3 percent were defective in that they contained holes.

**LABEL, IN PART:** (Package) "12 Dean's Peacocks Reservoir Ends."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "For Your Protection \* \* \* An Aid In Preventing Venereal Disease" were false and misleading as applied to an article containing holes.

**DISPOSITION:** September 29, 1950. Default decree of condemnation and destruction.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS**

**DRUGS FOR HUMAN USE\***

**3211. Misbranding of Imdrin. U. S. v. 2,100 Bottles \* \* \*. (F. D. C. No. 26977. Sample No. 20470-K.)**

**LIBEL FILED:** On or about April 14, 1949, Western District of Missouri; amended libel filed on February 2, 1950, Southern District of Ohio.

**ALLEGED SHIPMENT:** On or about December 21, 1948, and January 5, 7, and 14, 1949, by the Rhodes Pharmacal Co., Inc., from Cleveland, Ohio.

**PRODUCT:** 2,100 72-tablet bottles of *Imdrin* at Kansas City, Mo. Examination disclosed that each tablet of a portion of the product contained 2 grains of aspirin, 1.4 grains of manganese salicylate, 2.3 grains of calcium succinate, 0.19 grain of caffeine, and some thiamine, and that each tablet of the other portion of the product contained 2 grains of aspirin, 1.6 grains of sodium salicylate, 1.56 grains of calcium succinate, 0.16 grain of caffeine, and 1 mg. of thiamine.

**LABEL, IN PART:** "Imdrin \* \* \* Each tablet contains: Manganese Salicylate, Calcium Succinate, Acetylsalicylic Acid, Thiamine Chloride (1 mg.) and Caffeine" or "Imdrin \* \* \* Each tablet contains: Sodium Salicylate, Calcium Succinate, Acetylsalicylic Acid, Thiamine Chloride (1 mg.) and Caffeine."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements and designs appearing in the labeling of the article, namely, on a placard entitled "Rheumatic-Arthritic Sufferers," in a leaflet entitled "Amazing New Imdrin," and on a sheet entitled "Imdrin Fastest Selling Most Heavily Advertised Rheumatic-Arthritic Item," were false and misleading. The statements and designs represented and suggested that the article was adequate and effective for the treatment and cure of all types of arthritis and rheumatism; that the article contained no drugs; that it would give the fastest pain relief in

\*See also Nos. 3201, 3208-3210.