

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS

3521. Misbranding of Oxylin antiseptic tablets and Nef-Tex tablets. U. S. v. Louis E. Evons (Drexel Laboratories), and Meredith Evons. Pleas of guilty. Fine of \$350 against each defendant. (F. D. C. No. 30563. Sample Nos. 48797-K, 67509-K, 73621-K, 73946-K, 73947-K, 81007-K, 81107-K.)

INFORMATION FILED: April 17, 1951, Eastern District of Pennsylvania, against Louis E. Evons, trading as Drexel Laboratories, Drexel Hill, Pa., and Meredith Evons, manager.

ALLEGED VIOLATION: On or about April 29 and December 13, 1949, and February 7 and 14, March 3, and May 10, 1950, the defendants caused quantities of *Oxylin antiseptic tablets* and *Nef-Tex tablets* to be introduced and delivered for introduction into interstate commerce, at Upper Darby and Drexel Hill, Pa., for delivery to Newton, East Orange, Flemington, and Newark, N. J., Albany, N. Y., and Baltimore, Md.

Between February 12 and May 8, 1950, while a number of *Oxylin antiseptic tablets* were being held for sale at the Drexel Laboratories after shipment in interstate commerce from Camden, N. J., the defendants caused a number of the tablets to be repacked and relabeled, which acts resulted in the tablets being misbranded.

NATURE OF CHARGE: *Oxylin antiseptic tablets*. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. The statements represented and suggested that the article was an intestinal and urinary antiseptic; that it would be efficacious to arrest fermentation and allay irritation; and that it would be efficacious in the treatment of hyperacidity, intestinal toxemia, diarrhea, amebic and bacillary dysentery, bed wetting, gonorrhoea, nephritis, pyelitis, cystitis, pyuria, intestinal grippe, influenza, and the common cold. The article was not an intestinal and urinary antiseptic, and it would not be efficacious for the purposes represented. Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients; and it failed to bear a label containing the common or usual name of each of the active ingredients since it contained boric acid as one of its active ingredients, and the label of the article failed to declare the presence of boric acid. Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Dosage: Adults, 3 tablets swallowed with water on an empty stomach, 3 or 4 times daily. In acute or stubborn cases increase dosage to three tablets every two hours. Children, one tablet, four times daily," since such use of the article may result in boric acid poisoning.

Nef-Tex tablets. Misbranding, Section 502 (a), certain statements in the labeling of the article, which included an accompanying brochure headed "Nef-Tex Tablets," were false and misleading. The statements represented and suggested that the article would be efficacious to inhibit bacteria, arrest fermentation, remove the cause of intestinal and urinary irritations, and give quick relief from grippe and the common cold. The article would not be efficacious for the purposes represented.

DISPOSITION: September 11, 1951. Pleas of guilty having been entered, the court imposed a fine of \$350 against each defendant.