

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6312. Caffeine tablets and amphetamine sulfate tablets. (F.D.C. No. 44534. S. Nos. 31-026/9 R.)

QUANTITY: 16 btls., each containing 1,000 *amphetamine sulfate tablets*, 4 1,000-tablet btls. of orange-colored *caffeine tablets*, 7 1,000-tablet btls. of green-colored *caffeine tablets*, and 1 1,000-tablet btl. of white *caffeine tablets* at Meridian, Miss., in possession of the Meridian Police Dept., after having been taken from the possession of J. D. Cox of Russellville, Ala.

SHIPPED: On an unknown date, by J. D. Cox, from outside the State of Mississippi.

LIBELED: 4-27-60, S. Dist. Miss.

CHARGE: 502(b)—while held for sale, the articles (all lots) failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents in terms of numerical count; 502(e) (1)—the labels of the articles failed to bear the common or usual name of the drugs: 502(f) (1)—the labels of the articles (all lots) failed to bear adequate directions for use and the article of *amphetamine sulfate tablets* was not exempt from that requirement since it was a prescription drug found in the possession of persons not lawfully engaged in distributing or dispensing a prescription drug; and 503(b) (4)—the article of *amphetamine sulfate tablets* was subject to Section 503(b) (1) and the article failed to bear the label statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 6-30-60. Default—destruction.

6313. Foley basic urinary antiseptic tablets. (F.D.C. No. 44589. S. No. 30-837 R.)

QUANTITY: 792 individually ctn'd. btls. at Foley, Ala., in possession of Foley & Co.

SHIPPED: The article in the bottles was repacked and labeled, as described below, by the dealer from bulk stock shipped on 11-18-59, from Chicago, Ill.

LABEL IN PART: (Btl.) "144 Tablets Foley Basic Urinary Antiseptic Tablets
Active Ingredients: Methenamine 2½ gr. Calcium Mandelate 2.7843 gr.
Manufactured for Foley & Company, Chicago, Ill. * * * Directions * * *
Read Treatment Leaflet."

ACCOMPANYING LABEL: Leaflets in carton entitled "Getting up Nights . . .
Can you Break the Habit?" and "Foley & Company * * * Dear Customer:."

LIBELED: 5-23-60, S. Dist. Ala.

CHARGE: 502(a)—when shipped and while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for all conditions such as backaches, painful passage, frequent urination, and sagging muscles, resulting from bladder infections; and 503(b) (4)—the article was subject to 503(b) (1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9-1-60. Consent—claimed by Foley & Co. and relabeled.