

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 13573

become treatable with "Aristocort", without revealing the fact that patients with edema associated with a poor glomerular filtration rate are just as untreatable with Aristocort as they are with any other steroid, and (2) through the use of the statement: "Classic problems, such as salt and water retention, edema, overstimulated appetite, excessive weight gain, hypertension and euphoria, are unlikely to occur," without reporting that one of the major characteristics of this drug is its tendency to produce weight loss far more often than other steroids, due either to excretion of water, depression of appetite or protein catabolism, which weight loss is undesirable in some patients.

The advertising for Pathibamate tablets appearing in the September 1965, issue of *Archives of Internal Medicine* caused the drug to be misbranded within the meaning of 21 U.S.C. 352(n), in that it did not adequately present the information, as found in the labeling accepted as part of the approved new-drug application, concerning those side effects and contraindications which are pertinent to the uses suggested in the advertisement and for any other use for which the drug is commonly prescribed, as required by regulation 21 CFR 1.105(e) in that the following information is omitted:

1. Hypotensive crises, anuria, anaphylaxis, and stomatitis and proctitis are possible side effects.

2. Allergic or idiosyncratic reactions may develop in patients who have had only 1 to 4 doses of meproamate and have not had previous contact with the drug.

3. The drug is contraindicated in cases of known hypersensitivity to meproamate.

4. If severe reactions or idiosyncracies occur, use of the drug should be discontinued; and the drug should be administered cautiously to patients "... who are hypersensitive to sympathomimetic compounds, who have coronary or cardiovascular disease or who are severely hypertensive."

EVIDENCE OF VIOLATIVE SHIPMENT

Counts I and II: (Artane Elixir)

The sample was collected at Lederle Laboratories' branch warehouse located at 6100 East 60th Street, Kansas City, Missouri, by Inspector Donald L. Oglesbay. The sample was identified by the branch manager of Lederle Laboratories' branch warehouse at Kansas City, Missouri, who furnished the collecting inspector with documents showing that Artane Elixir sampled was shipped by Lederle Laboratories Division, American Cyanamid Company, Pearl River, New York, on October 13, 1964, via Cooper-Jarrett, Inc.

Count III: (Aristocort)

The sample was collected at the New Jersey Wholesale Drug Company, 645 Glenwood Avenue, Hillside, New Jersey, by Inspector Kendrick M. Cole. The lot sampled was identified by William Prairie, the warehouse manager of New Jersey Wholesale Drug Company, Hillside, New Jersey, who said that the shipment was received from Lederle Laboratories Division, Pearl River, New York, on September 3, 1965, via a truck of the Oostdyke Trucking Company. On November 9, 1965, Inspector Cole obtained a copy of the August 16, 1965, issue of the *Journal of the American Medical Association* together with an appropriate affidavit from Peter J. Bonanno, M.D., whose office is located at 741 Teaneck Road, Teaneck, New Jersey.

Count IV: (Pathibamate)

The sample was collected at Bonis Division of Ketchum & Company, 119 Plane Street, Newark, New Jersey, by Inspector Kendrick M. Cole. The sampled lot was identified by Sylvanus Ficklin, warehouse manager of Konis Division of Ketchum & Company, Newark, New Jersey, who said that the shipment sampled was received on September 17, 1965, from Lederle Laboratories Division, Pearl River, New York. On November 15, 1965, Inspector Cole obtained from F. Weisbrod, M.D., 61 South Munn Avenue, East Orange, New Jersey, page 64-A of the September 1965 issue of *Archives of Internal Medicine* together with an appropriate affidavit signed by Dr. Weisbrod.

HEARING PURSUANT TO 21 U.S.C. 335

On December 1, 1965, Mr. Bertram H. Lebeis, Legal Department, American Cyanamid Company, appeared at a hearing held in the Food and Drug Admini-