BACKGROUND INFORMATION

"Artane" is a trademark held by Lederle Laboratories for the drug, trihexyphenidyl hydrochloride. At the time of the alleged violation, Artane was commonly prescribed for the management of all forms of Parkinsonism and for the prevention and control of extrapyramidal disorders due to central nervous system drugs.

"Aristocort" is a trademark held by Lederle Laboratories for the drug, triamcinolone. At the time of the alleged violation, Aristocort was commonly prescribed in the treatment of rheumatoid arthritis and associated syndromes, acute bursitis, fibrositis, myositis, tendinitis, and torticollis, vasomotor and allergic rhinitis, bronchial asthma, pulmonary emphysema, and pulmonary fibrosis, aginoneurotic edema, urticaria and serum sickness, dermatoses, psoriasis, disseminated lupus erythematosus and other collagen diseases, nephrotic syndrome, rheumatic fever, leukemia and other lymphomatous diseases, hemolytic diseases, eye disorders, congestive heart failure and edema.

"Pathibamate" is a trademark held by Lederle Laboratories for the drug, tridihexethyl chloride in combination with meprobamate. At the time of the alleged violation, Pathibamate was commonly prescribed in the treatment of organic and functional disorders of the gastrointestinal tract, especially when accompanied by anxiety, neurosis, or tension states and in the management of gastric and duodenal ulcers.

Lederle Laboratories submitted to the Food and Drug Administration a new-drug application for Aristocort which was approved on October 24, 1957, and one for Pathibamate which was approved on April 22, 1957. Artane Elixir was originally marketed under the provisions of an approved new-drug application, but in September, 1955, the article was no longer considered a new drug.

EVIDENCE OF ADULTERATION

Examination at laboratories of the Food and Drug Administration of a sample Artane Elixir which had been shipped in interstate commerce by the defendant revealed that the article contained about 75% of the amount of active ingredients declared on the labeling.

EVIDENCE OF MISBRANDING

The medical journal advertising for Aristocort tablets appearing in the August 16, 1965, issue of the *Journal of the American Medical Association* did not contain a true statement in brief summary of the side effects, contraindications and effectiveness of Aristocort tablets, in that reference to the following information, which appeared in the labeling accepted as part of the approved new-drug application for Aristocort, was omitted:

1. The administration of anti-inflammatory steroids, such as Aristocort, has catabolic effects, and this, coupled with the anorexia frequently associated with the use of Aristocort, may produce a weight loss, and a steroid myopathy with advanced muscle weakness.

2. Aristocort may produce the following potentially serious side effects: moon face, striae, acne, buffalo hump, osteoporosis, spontaneous fractures, amenorrhea, aggravation of infection, psychotic disturbances, thromboembolism, gastrointenstinal hemorrhage, hyperglycemia, headache, insomnia, fatigue, hirsutism, vertigo and rarely necrotizing angitis; and necrotizing esophagitis and acute pancreatitis have occurred during corticosteroid therapy and may be caused by such therapy.

3. Caution should be exercised in the prolonged use in children because of the possibility of growth suppression.

4. It is important that therapy be withdrawn gradually after prolonged treatment. Adequate supportive measures, increase in dose or ACTH supplementation are indicated when undue stress occurs during or after triamicolone therapy and, if severe reactions or idiosyncracies are encountered, the drug should be discontinued and appropriate measures instituted.

5. Edema may occur, particularly in situations where the glomerular filtration rate cannot increase, such as in renal disease.

The advertisement for Aristocort further caused the drug to be misbranded within the meaning of 21 U.S.C. 353(n), in that the promotional text did not fairly show the effectiveness of the drug and lacked fair balance in its presentation as required by regulation 21 CFR 1.105(e), in that: (1) it implied that patients previously considered untreatable because they are "steroid risks"