for use, that such drug was a new drug recommended for certain uses and no approval of a new drug application was effective with respect to such uses; and that the advertisements for the drug did not present true statements of the effectiveness of the drug since such ads contained false and misleading representations concerning the efficacy of the drug for acute myocardial infarction and for stimulating collateral circulation.

In addition we recommended prosecution with respect to the drug Proloid on the basis of advertisements which would mislead physicians into believing that Proloid was the drug of choice in the treatment of myxedema and that cardiac complications could be avoided.

The Department of Justice in Washington declined prosecution because it disagreed with our interpretations of what the Peritrate and Proloid ads represented and suggested and because the defendant had ceased the advertising and labeling practices complained of with respect to Peritrate.

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OCTOBER 24, 1966.

In reply refer to F.D.C. No. 53050.
The Honorable ATTORNEY GENERAL,
*Department of Justice,*
*Washington, D.C.*

DEAR MR. ATTORNEY GENERAL: We request the institution of criminal proceedings under the Federal Food, Drug, and Cosmetic Act, against Lederle Laboratories Division, American Cyanamid Company, a corporation, Pearl River, New York.

The offenses complained of occurred during the period from about October 18, 1964, to about September 15, 1965, and involve the introduction into interstate commerce at Pearl River, New York, for delivery to Kansas City, Missouri, and Hillside and Newark, New Jersey of three articles of drugs: Artane (Trihexyphenidyl Hydrochloride) Elixir, Aristocort (Triamicinolone) tablets, and Pathibamate–400 (Tridihexethyl Chloride-Meprobamate) tablets.

There are transmitted herewith a suggested form of criminal information and the following exhibits:

(1) Copies of Notice of Hearing.

(2) Copies of bottle labels for Artane Elixir, Aristocort tablets and Pathibamate tablets.

(3) Copies of package insert labeling (the approved New Drug Application labeling) for Aristocort and Pathibamate.

(4) Copies of package insert labeling for Artane Elixir.

(5) Copies of cartons for Aristocort tablets and Pathibamate tablets.

(6) Copy of the advertisement for Aristocort tablets which appeared in the *Journal of the American Medical Association* for August 16, 1965, and a copy of the advertisement for Pathibamate tablets which appeared in the *Archives of Internal Medicine* for September, 1965.

SECTIONS OF ACT INVOLVED

The Information charges violation of 21 U.S.C. 331(a) in that the defendant caused the introduction into interstate commerce of articles of drug which were adulterated and misbranded (Artane Elixir) or misbranded (Aristocort tablets and Pathibamate tablets). Further, the articles were prescription drugs within the meaning of 21 U.S.C. 353(b)(1)(B) (Artane Elixir), or of 21 U.S.C. 553(b)(1)(C) (Aristocort and Pathibamate).

It is alleged that the Artane Elixir was adulterated within the meaning of 21 U.S.C. 351(c) in that its strength differed from that which it was represented to possess, and also misbranded under 21 U.S.C. 352(a) in that it did not contain the quantity of trihexyphenidyl hydrochloride declared on the label.

It is also alleged that the Aristocort tablets and the Pathibamate tablets were misbranded within the meaning of 21 U.S.C. 352(n) in that the defendant failed to include in the advertisements caused to be issued by it with respect to the drugs in the August 16, 1965, issue of the *Journal of the American Medical Association* (Aristocort), and the September, 1965, issue of the *Archives of Internal Medicine* (Pathibamate), a true statement of information in brief summary relating to side effects, contraindications and effectiveness of such drugs as required by regulations, 21 CFR 1.105 (e) and (f)(2).