JUNE 24, 1966.

In reply refer to F.D.C. No. 52397.
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 Bristol-Myers Company, a corporation trading and doing business under the name of Bristol Laboratories Division of Bristol-Myers Company at Syracuse, New York. The offenses complained of occurred on or about May 11, 1965 and September 9, 1965 and involved the introduction into interstate commerce at South Hackensack, New Jersey, for delivery to Pittsburgh, Pennsylvania, of prescription drugs, namely, "Salutensin", a combination of Saluron (hydroflumethiazide), Reserpine, and Protoveratrine A, and "Prostaphlin" (sodium oxacillin), both of which were misbranded.

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

A. Copies of Notices of Hearings.
B. Bottle labels.
C. Package inserts (the Salutensin approved NDA labeling and the Prostaphlin approved antibiotic labeling).
D. Copy of Prostaphlin monograph on pages 563 and 564 of the Physicians' Desk Reference, 1965 Edition.
E. Copy of Salutensin advertisement in the American Journal of Cardiology of November, 1964.
F. Copies of Salutensin Mailing Pieces.
G. Copy of Salutensin monograph on page 654 of the Physicians' Desk Reference, 1965 Edition.
H. Copy of Salutensin Mailing Piece SH 4950–1 (October 1961).

SECTIONS OF THE ACT INVOLVED

The Information charges violations of 21 U.S.C. 331(a) in that the defendant caused the introduction into interstate commerce of the above mentioned drugs which were misbranded as hereinafter described.

I—*Salutensin:* The drug was misbranded when introduced into interstate commerce within the meaning of 21 U.S.C. 352(n) in that defendant failed to include in an advertisement caused to be issued by it in the November 1964 edition of the American Journal of Cardiology a true statement of information in brief summary form relating to the drug's effectiveness, side effects, and contraindications as required by regulation 21 CFR 1.105 (e) and (f). The drug was further misbranded within the meaning of 21 U.S.C. 352(f)(1) in that its labeling failed to bear adequate directions for use, the drug not being exempt from such requirement since it was a prescription drug which was also a new drug subject to 21 U.S.C. 355 and the labeling namely two mailing pieces identified as SH 3852 RV and SH 3919 RV–2 and the monograph appearing in the 1965 Edition of the Physicians' Desk Reference was not, as required by regulations, substantially the same as the labeling authorized by the new drug application for the drug.

II—*Prostaphlin:* The drug was misbranded within the meaning of 21 U.S.C. 352(f)(1) in that the labeling of the drug failed to bear adequate directions for use. Nor was the drug exempt from such requirement since it was a prescription drug which was an antibiotic drug subject to 21 U.S.C. 357 and its labeling, namely its monograph, set forth in the 1965 edition of the Physicians' Desk Reference, was not, as required by regulations 21 CFR 1.106(b)(4), substantially the same as the labeling required as a condition for its certification nor did it provide adequate information for use under which a physician could use the drug safely and for the purposes for which it was intended. (See 21 CFR 146.2). It was further misbranded under 21 U.S.C. 352(1) in that the monograph appearing in the 1965 Physicians' Desk Reference is labeling which had not been submitted to the Commissioner of Food and Drugs as required by the Antibiotic Regulations, 21 CFR 146.2(b). (See also 21 CFR 146.4(a)(1)).

BACKGROUND INFORMATION

I—"Salutensin" is a trade-mark held by Bristol Laboratories for the drug, which is a mixture of Saluron (hydroflumethiazide), Reserpine, and Protovera-