trine A. At the time of the alleged violation, Salutensin was commonly prescribed for the treatment of hypertension and cardiovascular disease.

Bristol Laboratories submitted to the Food and Drug Administration a new-drug application for Salutensin which was approved on June 20, 1960.

The advertisement for Salutensin which appears in the November 1964 edition of the American Journal of Cardiology is a two page ad containing representatons relating to the effectiveness of the drug and statements concerning certain side effects and precautions applicable to it.

Salutensin Mailing Pieces, which are identified as "SH 3852 RV" and "SH 3919 RV–2", were designed by Bristol Laboratories. These four page mailing pieces were printed in September 1963. They contain representations relating to the effectiveness of the drug and statements concerning certain side effects and precautions applicable to the drug. The two aforesaid mailing pieces were distributed for Bristol Laboratories by Fisher-Stevens, Inc., a service organization, of Clifton, New Jersey as follows:

(1) On May 26, 1964, 75,131 of the "SH 3852 RV" Mailing Pieces were mailed to all General Practitioners, Doctors of Internal Medicine, and Cardiologists under 65 in private practice in the United States.

(2) On July 15, 1964, 75,145 of the "SH 3919 RV–2" Mailing Pieces were mailed out to the above identified physicians in the United States.

The May 1964 mailing was sent to 4,899 and the July 1964 mailing to 4,794 physicians in the state of Pennsylvania. Fourteen percent of these Pennsylvania physicians are located in Allegheny County which includes the city of Pittsburgh.

The 1965 edition of Physicians' Desk Reference, published by Medical Economics Inc., contains on page 564 a monograph for Salutensin. The PDR is published annually in cooperation with the subscribing manufacturers. The purpose of the PDR is to make available to the physician "essential prescription information on major pharmaceutical specialties". Information appearing in the PDR, however, is solely that furnished by the manufacturer. This is made clear by the "foreward" in the 1965 Edition which contains the following statement: "The function of the publisher is the compilation, organization, and distribution of the information. Each product description has been prepared by the manufacturer, and edited and approved by the manufacturer's Medical Department, Medical Director, or Medical Consultant."

An approved package insert for Salutensin bearing the date June 1963 details the side effects, warnings and precautions that are associated with the drug. It is clear that the manufacturer, Bristol-Meyers, had ample time prior to submission of the monograph for the 1965 edition of the PDR and before distribution of the two mailing pieces, to include this information contained in the approved package insert.

II—"Prostaphlin" is a trade-mark held by Bristol Laboratories for the antibiotic drug, sodium oxacillin. At the time of the alleged violations, Prostaphlin was commonly prescribed in the treatment of infections due to penicillin G-resistant Staphlococcus aureus, including skin and soft tissue infections, respiratory tract infections, genitourinary tract infections, osteomyelitis, bacteremia, septicemia and enterocolitis due to penicillin G-resistant staphlococci.

The 1965 edition of the Physicians' Desk References contains on pages 563 and 564 a monograph for Prostaphlin. As already indicated the information supplied in the PDR is wholly provided by the manufacturers of the drugs involved. The package insert labeling for Prostaphlin represents one of the specimens of labeling which were submitted to the Commissioner of Food and Drug on January 27, 1965 with a request for certification of the batch of Prostaphlin identified by Lot No. B 5312 from which the alleged shipment of Prostaphlin was subsequently made. Such labeling contained the four relevant hazards, contraindications, side effects, and precautions complained of herein. The copy of the Prostaphlin package insert bears the date August 1963. This proves conclusively that the firm knew about these conditions and had more than adequate time to include them in the 1965, and probably even in the 1964, Edition of the Physicians' Desk Reference.

EVIDENCE OF MISBRANDING

I—Salutensin:

21 U.S.C. 352(n) (*Regulation 1.105 (e) & (f)*).—In regard to the advertisement in the November 1964 American Journal of Cardiology, examination has shown that the advertisement failed to contain a true statement in "brief