it failed to include the monograph of said drug which appeared in the 1965 Edition of the Physicians' Desk Reference. (See 21 CFR 146.2(b) and 21 CFR 146.4(a)(1)).

EVIDENCE OF VIOLATIVE SHIPMENTS

On June 16, 1965, Food and Drug Inspector Joseph S. Slayton collected a sample of Salutensin from a lot of 72 60-tablet bottles which were held at McKesson and Robbins, Inc., Pittsburgh, Pennsylvania. A copy of an invoice and shipping records in the form of a motor express bill of Lading and/or freight bill showed that the lot had been received from the defendant's South Hackensack, New Jersey warehouse on or about 5/13/65. Inspector Slayton also obtained from Dr. James K. Spence of Pittsburgh, Pennsylvania a statement that he is a regular subscriber of the publication entitled "The American Journal of Cardiology." The doctor further identified pages 41 and 42 of the Salutensin advertisement in this publication bearing a November 1964 issue date.

On January 17, 1966, Food and Drug Inspector Alfred M. Levy obtained a statement from Donald J. Tierney, Production Manager of Fisher-Stevens, Inc. (Mailing Service for Bristol Laboratories) attesting to the fact that a total of 9,093 four page mailing pieces identified as SH 3852 RV and SH 3919 RV-2 and relating to Salutensin were mailed to physicians in Pennsylvania, on May 26, 1964, and July 15, 1964. Actual samples of these mailing pieces were also identified and furnished to the inspector.

On October 29, 1965 Food and Drug Inspector Joseph P. Brochetti collected a sample of Protaphlin from a lot of 10 48-capsule vials which were held at McKesson & Robbins Drug Division, 445 Fort Pitt Boulevard, Pittsburg, Pennsylvania. A copy of an invoice, the bill of lading, receiving record and dealer's statement showed that the lot had been received from the defendant's South Hackensack, New Jersey warehouse on or about September 12, 1965.

HEARING PURSUANT TO 21 U.S.C. 355

Pursuant to the Notice of Hearing regarding Salutensin dated August 9, 1965, Dr. Harold Frediani of Bristol Laboratories called the Food and Drug Administration's Buffalo District office on August 11, 1965 and was provided with details concerning the specific charges involving representations in the medical journal advertisement of November 1964 and in the labeling referred to as mailing pieces SH 3852 RV and SH 3919 RV-2.

The Hearing was originally scheduled for August 24, 1965 but was subsequently rescheduled at the request of the citee for September 7, 1965. The firm's answer was in the form of a 16 page letter dated September 3, 1965. The letter bore the signature of Hubert C. Peltier, M.D., Medical Director of Bristol Laboratories. This written answer denied all allegations. It maintained that the advertisement complained of complied with all pertinent requirements of the law. Likewise, the answer maintains that the mailing pieces involved contained adequate directions and information for the practitioner. The firm contended that the Salutensin advertisement in the November 1964 issue of the American Journal of Cardiology constituted an "alerting device" when read by the physician, and further referred the physician to the official package circular. The inference was that the advertisement "in its entirety" included package insert information not present in said advertisement. The firm likewise denied that the mailing pieces SH 3852 RV and SH 3919 RV-2 failed to contain full disclosure relative to side effects and warnings, etc. They contended the pertinent information given was all that a physician needed in order to use the drug; and that only unnecessary elaboration contained in the official package circular had been omitted. Throughout the written response, the firm contends and infers that many of the cautionary and warning statements, (although present in approved labeling), are superfluous and would not be needed by a physician, who would be aware of these omitted statements. The answer further indicated that the respondents would appreciate meeting with appropriate persons in the Washington headquarters of the Food and Drug Administration to discuss the matter with a view toward preventing such future differences.

Representatives of the firm met with Food and Drug Administration officials in Washington on October 11, 1965. The majority of the violations were discussed and the firm promised corrections in both future Salutensin advertisements and mailing pieces.