Pursuant to the Notice of Hearing regarding Prostaphlin dated November 4, 1965, and setting the Hearing date for November 17, 1965, the firm submitted an answer in the form of a four page letter dated November 16, 1965, signed by Hubert C. Peltier, M.D., Medical Director of Bristol Laboratories. The firm's answer, in essence, denied the charges made by the Government. However, it also included a somewhat corrected galley proposed for the 1966 Physicians' Desk Reference relative to the Prostaphlin monograph.

CONCLUSIONS

We believe that the factors which have been set forth in some detail above show that the labeling and advertisements used by this firm have not met the standards required by law. The omissions and deceptive statements involved were numerous and serious. Moreover, the required warnings were already well known to the company. As to Salutensin they were set down in the New Drug Application labeling and as to Prostaphlin they were included in the labeling submitted prior to antibiotic certification (package insert). In drug advertising the law does not provide for product touting or "puffing" when it entails a compromise in the requirement of full disclosure. The advertisement and mailing pieces involved in the Salutensin charge are replete with half-truths designed more to boost sales than to provide a physician with the information essential to the proper and safe prescription of that drug. As to Prostaphlin not only did the company fail to submit the Physicians' Desk Reference labeling as part of its request for batch certification as specifically required by regulations (21 CFR 146.2(b)) but the monograph which it did place in the Physicians' Desk Reference was at serious variance with the existing approved package insert. More oversight or carelessness cannot excuse the violations complained of here. The manufacturers of potent drugs, better than others, know the potential hazards of their products. Busy physicians should and must be able to rely on statements concerning a product without referring back to the original source to look for inconsistencies and contraindications. We believe the prosecution is fully warranted.

WITNESSES

The principal witnesses in this case will include the government inspectors who collected samples of the two drugs involved; witnesses to establish the interstate shipment of the drugs, the issuance of the PDR, mailing pieces and advertisement; medical officers from the Food and Drug Administration's Bureau of Medicine who will testify concerning the approved New Drug Application for Salutensin, the certification for this batch of Prostaphlin, the approved labeling and the serious nature of the alleged misbranding.

It is requested that if the form of Information is amended, that the United States Attorney furnish us with a copy thereof, and that we be kept advised of the progress and disposition of the case. Upon request, we shall render every further assistance.

Very truly yours,

WILLIAM W. GOODRICH,
Assistant General Counsel,
Food and Drug Division.

MARCH 26, 1969.

Re Bristol-Myers Co.—Alleged Violation of the Federal Food, Drug, and Cosmetic Act, F.D.C. No. 52397

MR. WILLIAM W. GOODRICH,
Assistant General Counsel, Food, Drug, and Environmental Health Division, Department of Health, Education, and Welfare, Washington, D.C.

DEAR MR. GOODRICH: We have carefully considered the request for prosecution of the above-mentioned company for alleged violations of the Federal Food, Drug, and Cosmetic Act stemming from its promotional activity in the field of advertising and labeling for the drugs Salutensin and Prostaphlin in 1965.

Since this matter was first referred to us the trial of the *Abbott* case, while unsuccessful, established a judicial precedent for the Government's contention that the monographs appearing in the Physicians Desk Reference are labeling. We understand that the Bristol-Myers Co. and the industry in general have accepted this determination and have been more careful to make certain that