We have noted that Mr. Goodrich strongly disagrees with your analysis of the discrepancies between the monograph and the approved labeling. In view of the decision of Judge Lepold in the *Abbott* case, we think that your point may be well taken but the question is impossible to evaluate in the absence of expected testimony. It would appear that the nature of these differences is a matter that could best be decided after discussion with medical experts of the Food and Drug Administration, who would be called at witnesses, as well as a combination of the statements of any outside experts who would be expected to testify on behalf of the Government. It is, therefore, suggested that you should interview the appropriate Food and Drug Administration experts and examine the statements of expected witnesses before making a final decision.

While it appears that the subject has seen the error of its ways and has voluntarily complied with the desires of the Agency both with respect to its P.D.R. labeling and advertising practices, we believe you should balance these factors with the Agency's opinion as to the seriousness of the offense and the necessity for criminal action. We suggest that the Court's attitude toward this kind of an offense may be ascertained at the time it imposes sentence in the *Ciba* matter, which, we understand, is expected to take place shortly and may be considered by you in evaluating this matter.

Accordingly, your reconsideration of this matter in the light of Mr. Goodrich's comments will be appreciated. We trust that you will advise us in your final decision.

Sincerely,

FRED M. VINSON, Jr.,
Assistant Attorney General,
Criminal Division.

By HAROLD P. SHAPIRO,
Chief, Administrative Regulations Section.

UNITED STATES DEPARTMENT OF JUSTICE,
UNITED STATES ATTORNEY,
FOR THE DISTRICT OF NEW JERSEY,
Newark, N.J., October 30, 1968.

Attention Harold P. Shapiro, Chief, Administrative Regulations Section.
Re Syntex Laboratories, Inc., F.D.C. No. 53222—Federal Food, Drug and Cosmetic Act. Your Ref: FMV:JWK:mc, 21-48-353.

DEPARTMENT OF JUSTICE,
Washington, D.C.

DEAR MR. SHAPIRO: At your suggestion we have again reconsidered our file in the above-referenced matter and have again concluded that the case lacks prosecutive merit for substantially the reasons set forth in our letter dated May 21, 1968.

We do not believe that interviews with medical personnel concerning the discrepancies between the monograph and approved labeling would affect our opinion regarding the prosecutive merits of this action. The regulations themselves give the company some license to synopsize the material of the approved labeling in the monograph. Even if medical personnel could convince us that there were substantial differences and that we could in fact carry our burden of proof, we feel that prosecution of this offense that occurred over three years ago would not be in the best interests of the Federal Government, especially in light of the fact that revised and current monographs do comply with the regulations.

On October 25, 1968, the Ciba Pharmaceutical Company was fined $200.00 on each count of a two count Information charging violations similar to those here. In view of the time expended on this case by this office and by the Food and Drug Administration, we found this result most discouraging. In view of the factors outlined above and in our previous correspondence, we doubt that we could achieve a more staisfactory result in this matter.

Very truly yours,

DAVID M. SATZ, Jr.,
U.S. Attorney.
By MARLENE GROSS,
Assistant U.S. Attorney.