WITNESSES

The principal witness in this case will be the Government Inspectors who collected the samples and made the inspections, the Government Analyst who analyzed the samples, witnesses to establish the interstate origin of the samples and the issuance of the advertisements, and medical officers of the Food and Drug Administration's Bureau of Medicine who can testify as to the approved new drug application, the approved labeling, and the serious nature of the alleged medical journal advertising misbranding.

It is requested that, if the form of Information is amended, the United States Attorney furnish us with a copy thereof; also, that he keeps us advised as to the progress of the case and its disposition.

The New York District Office of the Food and Drug Administration, located at 850 Third Avenue (at 30th Street), Brooklyn, New York 11232, Telephone: 788-1300, will arrange for the presence of the necessary witnesses and assist in the presentation of the case. Upon request, we will render such further assistance as may be possible.

Very truly yours,

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

APRIL 22, 1968.

Re Syntex Laboratories, Inc., F.D.C. No. 53222, Federal Food, Drug, and Cosmetic Act

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

DEAR MR. GOODRICH: In view of the expressions contained in your letter of March 1, 1968, we have re-examined our previous determination relative to prosecution of this matter. The reasons set out in your letter tend only to reinforce our opinion that this matter does not present a case for prosecution and is not a proper setting in which to attempt to sustain a judicial interpretation of the regulations issued pursuant to Section 352(n) of the Act.

We believe that any attempt to secure a judicial interpretation which will enlarge the meaning of the statutory terms on the basis of the meaning of the word "relating" as suggested by you would be frustrated by the factual situation. The difficulty inherent in any such attempt is that the labeling which was approved by the Food and Drug Administration contains the same words as are found in the statute and regulations, i.e., "side effects" and "contraindications." Under each heading, the specific items or conditions are listed. Many of the conditions which you now contend are side effects or contraindications are not listed under those headings in the labeling but are set out under other headings in the labeling. In a criminal prosecution, such a factual situation creates an impossible barrier to success. In all likelihood, the only result would be to obtain a judicial expression contrary to your desire. In passing, we consider the possibility that the court might find an analogy between the present situation and that of *Haynes* v. *United States*, —— U.S. ——, decided January 29, 1968, wherein the Supreme Court commented that "so much could not be derived from so little."

Moreover, the argument presented relative to the meanings of certain language used in the advertisement as compared to that of the labeling presents so fine and tenuous a distinction as to render conviction most unlikely. In other instances, the suggested violation appears to consist of a failure to furnish information which does not appear in the approved labeling.

Specifically, the argument that the statement in the advertisement that the drug is contraindicated in pregnancy is not satisfactory because the doctor should have been told to discontinue the drug "at the earliest possible sign of pregnancy" is untenable. Obviously, the physician is not going to use the drug to prevent pregnancy if the patient is pregnant. Neither would it seem logical to expect that a physician would continue its use after the patient became pregnant. Moreover, under the circumstances, any physician would be aware that contraindications of the drug in pregnancy can only mean that it should be discontinued if the patient becomes pregnant.

As to the necessity for discontinuance at the earliest possible sign, it will be observed that the approved labeling under the heading of "side effects" notes that symptoms "resembling early pregnancy" as well as changes in the men-