Your letter leads us to the conclusion that you do not contend that the advertisement for Norinyl claimed any use not included in the approved labeling but only that it did not set forth all the side effects with the specificity which the agency finds desirable. Your letter also states that it is your position that advertisements of new drugs subject to prescription use for which applications were approved after October 10, 1962, cannot contain any statement that is not in the approved New Drug Application.

We have observed that had the advertisement set forth as "side effects" some of the statements which you contend should have been there included such act would be a direct violation of the position stated above because the statements of the conditions allegedly omitted are *not* found under that heading in the approved labeling. Your contentions, therefore, seem to be diametrically opposed to your argument as to the necessity that the advertisement conform to the labeling.

Although we are declining prosecution based upon the alleged violations of the advertising provision of the Act, we do not have the same reservations concerning the violation alleged in Count I of the suggested form of information which relates to the use of improper labeling in the monograph in the *Physicians' Desk Reference.*

We are engaged in the process of redrafting that Count in accordance with the ideas expressed in our last communication. A copy of our communication to the United States Attorney will be forwarded to you when it is mailed.

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., May 21, 1968.

Attention Harold P. Shapiro, Chief, Administrative Regulations Section.
Re Syntex Laboratories, Inc., FDC 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: We have reviewed the file in the above-referenced matter and have concluded that the case lacks prosecutive merit.

We recognize that discrepancies between the monograph and the approved labeling do exist. However, the regulations themselves require only that the labeling be "substantially" the same as the labeling authorized by the approved new drug application. The word "substantially" certainly gave the company some license to synopsize the information contained in the approved new drug application. A reasonable doubt exists in our minds as to whether the labeling in the monograph is substantially different from the labeling in the approved new drug application, and we believe that a lay jury would also harbor such a doubt.

Moreover, the discrepancies between the monograph and the approved labeling do not appear to have been the result of a purposeful evasion of the regulatory requirements of the Administration but of an honest difference of opinion as to what was required under the regulations. In fact, at the hearing held on April 8, 1966, the firm offered to obviate all future difficulties by submitting sample advertising and monographs to the Food and Drug Administration before publication.

In closing, we note that the offense complained of occurred in September, 1965, almost three years ago. No indications of violations of the Food and Drug law subsequent to that date are reported. Prosecution at this rather late date would not be in the best interests of the Federal Government.

Very truly yours,

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