Turning to the reasons given in your letter of April 22, 1968, for declining to prosecute the advertising violations, we must reiterate what we have frequently said to your representatives, that the brief summary is required to disclose true information related to side effects, contraindications, and effectiveness as specified in our regulations, not merely the information headed "side effects" and "contraindications" in the approved labeling.

We are confident that any qualified expert would regard the information about clotting, calcium and phosphorus metabolism, effect on organ and endocrine functions, etc., as information related to "side effects" and "contraindication" as those terms were used in the 1962 Drug Amendments. The fact that the information in certain instances was headed "Thyroid Gland", etc., does not make it less information related to side effects than the material in the labeling under the heading "Side Effects." A mere reading of the package insert establishes this.

While criminal prosecutions do sometimes involve strict interpretations of regulations, there is "no canon against using common sense" in applying a criminal law.

As to the point you make that our understandings of what was said in the advertising are based upon tenuous constructions, we think we should have an opportunity to present these points to a court or jury with an explanation of their important medical significance.

Surely a jury would understand the need to warn a physician, and through him the patient, that a missed dose or a miscalculation in taking the oral contraceptive drug may result in pregnancy, and that if that occurs there is danger to the unborn child from continuing to take the drug. Telling the physician that the drug is contraindicated in pregnancy does not tell him what he really needs to know for his patient's safety in bearing a child. It is the need to alert the user to the hazard to the unborn child which may result from a missed dose or a miscalculation that calls for this early pregnancy warning.

On psychic depression, we have noted above that as late as January 1968, Syntex was still not properly presenting the message about this hazard to the profession. A corrective letter was necessary. What is missing in the ads is the warning that any patient with a history of psychic depression should be carefully observed (this means the patient should be followed much more closely than the routine patient) if a decision is made by the physician to prescribe the oral contraceptive. A statement that the drug is contraindicated in "severe depression" does not adequately advise the physician of the risk he runs with a patient who has had depression in the past but now has it under control.

Blood clotting has been a problem with these drugs for a long time. When these ads ran, the labeling was required to say that such episodes had occurred, that a causal relationship had not been established, and that the problem was under investigation. The ad said nothing about this. Instead, it said the drug was contraindicated in thrombophlebitis and pulmonary embolism (current or past). This is quite different from telling the physician that the cause and effect relationship of the oral contraceptive drugs to these serous complications, particularly in the older age groups, was then under scientific investigation.

As you know, this problem has caused a progressive strengthening of the warning as more experience has been gained.

Finally, we must express our disagreement with the idea that a drug company can use a literally true statement to convince prescribers that its products are superior to other identical products. A half-truth is still sometimes a great lie. Promotional practices with this class of products have been characterized by the use of such half-truths to gain marketing advantages. We have had to require several companies to discontinue such ads and to send letters of correction to the profession. For from being harmless puffing—which in any event is not tolerated in prescription drug advertisements—this kind of promotion affirmatively misrepresents both the effectiveness and the safety of the oral contraceptives.

We have written you at this length because of the serious consequences to the profession and to patients of improper prescription drug advertising.

Six million women are considered to be on oral contraceptive drugs at this time in the United States. Their safe use depends upon proper promotion of the drugs to the profession. Syntex has seriously failed in the instances cited in our recommended prosecution case.

Yours very truly,

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