

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 13607

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.*

SEPTEMBER 20, 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: Enclosed is a copy of our letter of even date to the United States Attorney at Newark, New Jersey, requesting that his office reconsider the above matter in light of your letter of May 21, 1968. Your attention is invited to our suggestion on page two that the United States Attorney interview the Food and Drug Administration experts who would be called as witnesses and review the expected testimony of non-Government experts who may also be called. We believe that such action is necessary to ascertain whether or not the differences between the P.D.R. and the approved labeling are substantial.

It is suggested that you arrange with the United States Attorney for him to interview the Food and Drug Administration experts and furnish him with a statement of the testimony which may be expected from any other experts who will appear for the Government.

Sincerely,

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

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

SEPTEMBER 20, 1968.

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

Mr. DAVID M. SATZ, Jr.,
*U.S. Attorney,
Newark, N.J.*

DEAR MR. SATZ: After receiving your letter of May 21, 1968, recommending that the above-captioned matter be closed without prosecution, we received a letter from Mr. Goodrich, Assistant General Counsel, Food and Drug Division, taking exception to your conclusions and requesting a further consideration. In view of the strong differences of opinion held by Mr. Goodrich, your office, and ourselves, we suggested that a meeting be arranged whereby all parties could discuss their views.

However, our efforts to arrange such a meeting have been to no avail, and since the matter is growing stale, we believe it is appropriate to forward a copy of Mr. Goodrich's letter. We understand that Mr. Goodrich's assistant, Mr. Gottlieb, has previously shown Miss Gross a rough draft of this letter so that she is familiar with its contents.

You will observe that Mr. Goodrich not only disagrees with your conclusion, that the alleged violations of the Act which relate to the monograph on the drug Syntex, which appeared in the *Physicians' Desk Reference* for 1965, do not justify criminal prosecution, but also with our decision that the alleged violations of the advertising provisions of the Act do not provide a basis for prosecution. Insofar as our decision on the latter problem is concerned, the views set forth in Mr. Goodrich's letter have long been known to us and were thoroughly considered at the time we reached our conclusion. They, therefore, are not, in our view, so persuasive as to result in a change of our views.