Gynecology, and the February 1, 1966, Edition of The American Journal of Obstetrics and Gynecology.

The headquarters of Syntex Laboratories, Inc., are presently located in Palo Alto, California, but manufacturing at the time of the alleged violations was carried out elsewhere. The drug in question was manufactured by Syntex Laboratories employees' using equipment located on the premises of Warner-Chilcott Laboratories, Inc., Morris Plains, New Jersey. This manufacturing operation was under the control of Syntex Laboratories, Inc. The shipments of the drug were made by the Syntex Laboratories Branch in Clark, New Jersey.

HEARING HELD PURSUANT TO 21 U.S.C. 335

A Notice of Hearing issued pursuant to 21 U.S.C. 335 on April 8, 1966, addressed to Syntex Laboratories, Inc., 1401 Hillview Drive, Palo Alto, California.

A personal response was made by Mr. Vincent Kleinfeld, Attorney for the firm, on April 21, 1966. Mr. Kleinfeld did not question the interstate nature of the shipments and did not deny that the Physicians' Desk Reference was accompanying labeling as is charged in Count I. Neither did he deny the firm's responsibility for the shipments, for the placing of the monograph in the Physicians' Desk Reference, nor for the placement of the advertisements in question in the November issues of the various medical journals.

Mr. Kleinfeld said that the firm had no intention of deliberately omitting information from the Physicians' Desk Reference or from medical journal advertising that they believe would have been desired by the Food and Drug Administration. He said that honest men can differ in opinions as to what is required under the regulations and that Syntex's doctors had believed their medical journal advertising and the monograph in the Physicians' Desk Reference were in full compliance with the law. Mr. Kleinfeld stated that he himself did not realize the full extent of the information desired by the Food and Drug Administration to appear in these publications.

Mr. Kleinfeld said he was helping the firm to set up the procedure for the development of advertising and labeling that will assure full compliance with the requirements of the Food and Drug Admiinstration. He had prepared and submitted to the Food and Drug Administration a new proposed monograph for the Physicians' Desk Reference to be published in the next quarterly supplement after it is approved by the Food and Drug Administration. He had also prepared a statement for use in medical journal advertising as soon as he obtained approval from the Food and Drug Administration. He stated that he was of the opinion that these proposals would meet all the points raised in the Notice of Hearing but that they would be changed if they were still not satisfactory to the Food and Drug Administration.

On June 21, 1966, Mr. Kleinfeld, and other representatives of Syntex Laboratories, Inc., met with representatives of the Food and Drug Administration in Washington, D.C. A proposed monograph for the Physicians' Desk Reference was submitted and discussed as was proposed material for journal advertising. The firm indicated an intention to comply with the recommendations and requirements of the Food and Drug Administration.

SEIZURES

No seizures were made of the shipments which are the subject of the proposed Information.

CONCLUSIONS

We have considered the representations which were made on behalf of the firm at the above hearing. However, we cannot ignore the facts which show that Syntex Laboratories, Inc., has had an extensive experience in the development of new drugs and their subsequent distribution in accordance with the new drug regulations; and that such firm was fully aware of the regulations which required that the contraindications and side effects set forth in the approved new drug application labeling be presented in the Physicians' Desk Reference monograph and in the medical journal advertisements.

In these circumstances and in the interest of protecting the health of the consuming public, it is our opinion that criminal prosecution is necessary to impress upon Syntex Laboratories, Inc., its responsibility for compliance with the law, and to deter other firms from similar violations of the law.