Cosmetic Act, against Syntex Laboratories, Inc., 1401 Hillview Drive, Palo Alto, California, and 45 Walnut Avenue, Clark, New Jersey. The offenses complained of occurred on or about September 29, 1965, November 18, 1965, and February 18, 1966, and involve the introduction into interstate commerce at Clark, New Jersey, for delivery to Berkeley, California, of quantities of Norinyl, a prescription drug.

There are transmitted herewith a suggested form of criminal Information and the following exhibits:

A. Copy of Notice of Hearing.
B. Carton and bottle labels.
C. Package insert (approved new drug application labeling).
D. Copy of monograph in 1965 Edition of Physicians' Desk Reference.
E. Copy of advertisements in the November 1, 1965, November 15, 1965, and February 1, 1966, Editions of The American Journal of Obstetrics and Gynecology; the November, 1965, and February, 1966, Editions of Obstetrics and Gynecology; and the February 14, 1966, Edition of Modern Medicine.

SECTIONS OF ACT INVOLVED

The Information charges violation of 21 U.S.C. 331(a) in that the defendant caused the introduction into interstate commerce of quantities of Norinyl which were misbranded as hereinafter described.

Count I.—The drug was misbranded within the meaning of 21 U.S.C. 352(f)-(1) in that its labeling failed to bear adequate directions for use and it was not exempt from such requirement since its labeling, a monograph in the 1965 Edition of the Physicians' Desk Reference, failed to comply with the requirements of regulations 21 CFR 1.106(b)(4)(i).

Counts II and III.—The drug was misbranded within the meaning of 21 U.S.C. 352(n) in that the defendant failed to include in advertisements caused to be issued by it in the (Count II) November 1 and 15, 1965, Edition of The American Journal of Obstetrics and Gynecology and the November, 1965, Edition of Obstetrics and Gynecology, and in the (Count III) February 1, 1966, Edition of The American Journal of Obstetrics and Gynecology, the February, 1966, Edition of Obstetrics and Gynecology, and in the February 14, 1966, Edition of Modern Medicine, a true statement of information in brief summary relating to the side effects and contraindications of the drug as required by regulations 21 CFR 1.105(e) and (f).

BACKGROUND INFORMATION

"Norinyl" is a registered trade name used by the defendant for a drug composed of 2 mg. of Norethindrone and 0.1 mg. of Mestranol. At the time of the alleged violations, Norinyl was commonly prescribed as an oral contraceptive.

Syntex submitted to the Food and Drug Administration a new drug application for Norinyl which was approved on March 5, 1964. At this time, the Commissioner of the Food and Drug Administration sent a letter to Syntex Laboratories, Inc., in which he said that the claims made in the labeling were limited by the representations made in the new drug application. The Commissioner also said that the approval of the new drug application in no way relieved Syntex Laboratories from complying with all of the provisions of the Federal Food, Drug, and Cosmetic Act.

The 1965 edition of the Physicians' Desk Reference, published by Medical Economics, Inc., bore a monograph for Norinyl which appeared on pages 962 and 963. The Physicians' Desk Reference is published annually in cooperation with the subscribing manufacturers. The purpose of the Physicians' Desk Reference is to make available to physicians information on major pharmaceutical specialties. Information appearing in the Physicians' Desk Reference is solely that furnished by the manufacturers. This is explained by the foreward in the 19th Edition which contains the following statement: "The function of the publisher is the compilation, organization, and distribution of the information. Each product description has been prepared by the manufacturer, and edited and approved by the manufacturer's Medical Department, Medical Director, or Medical Consultant."

EVIDENCE OF MISBRANDING

Count I.—The drug, Norinyl, which is a prescription drug and which is a new drug subject to 21 U.S.C. 355, was not exempt from the requirements of 21 U.S.C. 352(f)(1) that adequate directions for use appear in its labeling since