it failed to comply with the condition for exemption set forth in the regulations 21 CFR 1.106(b)(4). Such condition requires that, in case of a drug subject to 21 U.S.C. 355, the labeling be substantially the same as the labeling authorized by the approved new drug application for such drug. This was not true with respect to Norinyl because its labeling, the 1965 Edition of the Physicians' Drug Reference, failed to include the following information which was in the new drug application labeling:

(1) A statement concerning the length of experience with the drug, and that although no deleterious effect of the drug on pituitary, ovarian, adrenal or uterine function has been noted, the long-range effect on these and other organs must await more prolonged observation.

(2) The information regarding the possibility of pregnancy if the treatment schedule is not adhered to; and that, if the regular menses fail to appear and the treatment schedule has not been adhered to, or, if the patient misses two regular menstrual periods, the possibility of pregnancy should be resolved before resuming Norinyl. If pregnancy is established, Norinyl should be discontinued during the period of gestation, on the basis that virilization of the female fetus has been reported with oral use of progestational agents or estrogen.

(3) The important information regarding the possible causal relationship between progestational agents and intravascular clotting. In addition, the Physicians' Desk Reference labeling contained the statement "it provides maximum protection against unplanned pregnancy and minimizes undesirable side effects resulting in fewer patient dropouts" which statement was not supported by the approved new drug application labeling.

Counts II and III.—In regard to the advertisements upon which the misbranding charges are based, examination has shown that they omitted certain information which was in the new drug application labeling and that they included certain information which was not in such labeling. The nature of such information is alleged in the criminal Information. Because of such omission and of such inclusion, the advertisements failed to include true statements relating to the side effects and contraindications of Norinyl as required by regulations.

EVIDENCE OF VIOLATIVE SHIPMENTS

Count I.—A sample of two 100-tablet bottles of Norinyl was taken at random from a lot of ten such bottles in the shelf stock of the Permanente Services Pharmacy, South San Francisco, California, by Food and Drug Inspector Frank W. Scholl. The lot was identified by Donald E. Murray, Manager and Pharmacist in Charge of the Dapite Division of Permanente Services, Inc., Berkeley, California, who said that the lot had been received from Syntex Laboratories, Inc., Clark, New Jersey, on October 8, 1965, and subsequently shipped to the above-mentioned pharmacy. Mr. Murray supplied the Inspector with supporting documents.

Count II.—No physical sample was obtained. However, Donald E. Murray of the Dapite Division of Permanente Services said that his firm had received 36 twenty-tablet packages and 48 100-tablet bottles of Norinyl from Syntex Laboratories, Inc., Clark, New Jersey, on November 26, 1965. Mr. Murray supplied Inspector Frank D. Korun with supporting documents relating to the shipment. Mr. Richard Wickel, Assistant Administrator for the Samuel Merritt Hospital, Oakland, California, provided Inspector Korun with copies of advertisements for Norinyl which appeared in the November 1, 1965, and November 15, 1965, Editions of The American Journal of Obstetrics and Gynecology, and the November, 1965, Edition of Obstetrics and Gynecology.

Count III.—A sample of three 100-tablet bottles was taken by Food and Drug Inspector Frank Korun at random from a lot of 48 such bottles at the Dapite Division of Permanente Services, Inc., Berkeley, California. The lot was identified by Mr. Donald Murray, who said that the firm received the lot from Syntex Laboratories, Inc., Clark, New Jersey, on February 28, 1966. Copies of documents relating to the shipment were provided by Mrs. Florence Burns, an employee of Dapite. Mr. Richard Wickel, Assistant Administrator for the Samuel Merritt Hospital, Oakland, California, provided Inspector Korun with copies of advertisements for Norinyl which appeared in the February 14, 1966, Edition of Modern Medicine, the February, 1966, Edition of Obstetrics and