(c) (1) The oral contraceptives are restricted to prescription sale, and their labeling is required to bear information under which practitioners licensed to administer the drugs can use them safely and for the purpose for which they are intended. In addition, in the case of oral contraceptive drugs, the Commissioner concludes that it is necessary in the best interests of users that the following printed information for patients be included in the package dispensed to the patient:

"ORAL CONTRACEPTIVES (BIRTH CONTROL PILLS)

"The oral contraceptives are powerful, effective drugs. Do not take these drugs without your doctor's continued supervision. As with all effective drugs, they may cause side effects in some cases and should not be taken at all by some. Rare instances of abnormal blood clotting are the most important known complication of the oral contraceptives. These points were discussed with you when you chose this method of contraception.

"While you are taking this drug, you should have peridoic examinations at intervals set by your doctor. Notify your doctor if you notice any of the following:

"1. Severe headache.
"2. Blurred vision.
"3. Pain in the legs.
"4. Pain in the chest or unexplained cough.
"5. Irregular or missed periods."

(2) Providing this information to users may be accomplished by including it in each package of the type intended for the user as follows:

(i) If such package includes other printed materials for the patient (e.g., dosage schedules), the text of the information in subparagraph (1) of this paragraph shall be an integral part of the printed material and be in boldface type set out in a box, preceding all other printed text.

(ii) If such package does not include printed material for the patient, the text of the information in subparagraph (1) of this paragraph shall be provided as a printed leaflet in boldface type.

(iii) Include in each bulk package intended for multiple dispensing, a sufficient number of the information leaflets, with instructions to the pharmacist to include one with each prescription dispensed.

(d) Written, printed, or graphic materials on the use of a drug that are disseminated by or on behalf of the manufacturer, packager, or distributor to the patient, are regarded as labeling. The Commissioner also concludes that it is necessary that full information in lay language, concerning effectiveness, contraindications, warnings, precautions, and adverse reactions be incorporated prominently in the beginning of any such materials.

(e) The marketing of oral contraceptives may be continued if all the following conditions are met within 30 days of the date of publication of this section in the FEDERAL REGISTER.

(1) The labeling of such preparations shipped within the jurisdiction of the Act is in accord with paragraphs (c) (1) and (2), and (d) of this section.

(2) The holder of an approved new-drug application for such preparation submits a supplement to his new-drug application under the provisions of § 130.9(d) of this chapter to provide for labeling as described in paragraphs (c) and (d) of this section. Such labeling may be put into use without advance approval of the Food and Drug Administration.

All interested persons are invited to submit their views in writing, preferably in quintuplicate, regarding this proposal. Such views and comments should be addressed to the Hearing Clerk, Department of Health, Education, and Welfare Room 6–62, 5600 Fishers Lane, Rockville, Md. 20852, within 30 days following the date of publication of this notice in the FEDERAL REGISTER. Comments may be accompanied by a memorandum or brief in support thereof.

(Secs. 502 (a), (f), 505, 701(a), 52 Stat. 1050–53, as amended, 1055; 21 U.S.C. 352 (a), (f), 355, 371(a))

Dated: March 26, 1970.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

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