It tells women that "oral contraceptives are powerful, effective drugs" which should not be taken without a "doctor's constant supervision" and that "they may cause side effects in some cases and should not be taken at all by some."

This is the full statement:

"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 a periodic examination at intervals set by your doctor. Tell your doctor should 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."

After tomorrow's publication physicians, drug manufacturers and other interested parties will have 30 days to register comments and complaints with the FDA. Unless these are deemed sufficiently significant to warrant changes, the message will be included in every package of contraceptives in a few months' time.

[From the Federal Register, Vol. 35, No. 70, April 10, 1970, pp. 5962–5963]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE—FOOD AND DRUG ADMINISTRATION

[21 CFR Part 130]

NEW DRUGS

Proposed Statement of Policy Concerning Oral Contraceptive Labeling Directed to Laymen

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502 (a), (f), 505, 701(a), 52 Stat. 1050-53, as amended, 1055; 21 U.S.C. 352 (a), (f), 355, 371(a)) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120), it is proposed that he following new section be added to Subpart A of Part 130:

§ 130. Oral contraceptive preparations; labeling directed to the patient.

(a) The Food and Drug Administration is charged with assuring both physicians and patients that drugs are safe and effective for their intended uses. The full disclosure of information to physicians concerning such things as the effectiveness, contraindications, warnings, precautions and adverse reactions is an important element in the discharge of this responsibility. In view of this, the Administration has reviewed the oral contraceptive products, taking into account the following factors: the products contain potent steriod horomones which affect many organ systems; they are used for long periods of time by large numbers of women who, for the most part, are healthy and take them as a matter of choice for prophylaxis against pregnancy, in full knowledge of other means of contraception; and because of their indications they are sometimes used without adequate medical supervision. They represent, therefore, the prototype of drugs for which well-founded patient information is desirable.

(b) In view of the foregoing, it is deemed to be in the public interest to present to users of oral contraceptives factual information as to the risks and possible side effects associated with their use by requiring, as part of their labeling, appropriate information in lay language. The information would emphasize to the patient the need for continuing surveillance and supervision by a physician. The Commissioner of Food and Drugs is aware that this represents a departure from the traditional approach to the dissemination of information regarding prescription drugs via the doctor/patient relationship, and stresses that it is not intended to weaken or replace that channel, but rather because of the unusual pattern of use by these drugs, to reinforce the efforts of the physician to inform the patient in a balanced fashion of the risks attendant upon the use of oral contraceptives.