AMENDMENT TO H.R. 4368, AS REPORTED

OFFERED BY MRS. MILLER-MEEKS OF IOWA

At the end of the bill (before the spending reduction account), insert the following:

FDA GUIDANCE ON CHANGING MARKETING STATUS OF CONTRACEPTIVE DRUGS TO OVER-THE-COUNTER

SEC. ____.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Commissioner of Food and Drugs, for purposes of encouraging sponsors of oral contraceptive drugs to submit applications for the approval of oral contraceptive drugs to be marketed without being subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)), shall issue guidance that—

(1) provides a detailed description of the review process for the—

(A) approval of drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(B) marketing authorization of over-the-counter drugs under section 505G of such Act (21 U.S.C. 355h); and

(C) licensure of biological products under section 351 of the Public Health Service Act (42 U.S.C. 262);

(2) provides for background information on oral contraceptive drugs, including—

(A) the history of approval, marketing authorization, or licensure of oral contraceptive drugs under the provisions of law specified in paragraph (1);

(B) the standards used to grant such approval, marketing authorization, or licensure; and

(3) specifies the benefit-risk considerations that the Commissioner uses to determine whether to approve, authorize for marketing, or license oral contraceptive drugs; and

(4) details the Commissioner's efforts to facilitate the development of oral contraceptive drugs to be marketed without being subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(b) LABELING COMPREHENSION STUDY.—

(1) IN GENERAL.—The Commissioner of Food and Drugs shall complete a study on consumer com-

prehension of the labeling of oral contraceptive drugs.

(2) ISSUES TO BE STUDIED.—The study required by paragraph (1) shall address how the labeling of oral contraceptive drugs could be improved to increase consumer comprehension of the information conveyed in such labeling, including the proper use of such drugs and for whom such drugs are indicated.

(3) COMPLETION; PUBLICATION.—The Commissioner of Food and Drugs shall—

(A) not later than 1 year after the date of the enactment of this Act, complete the study required by paragraph (1); and

(B) publish the results of such study in conjunction with the issuance of the guidance required by subsection (a).

(c) ORAL CONTRACEPTIVE DRUG DEFINED.—In this section, the term ''oral contraceptive drug'' means a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) that—

(1) is used to prevent fertilization;

(2) is administered orally;

(3) is solely intended for routine use and not as an emergency contraceptive;

(4) does not include any drug, substance, or combination of drugs or substances used after fertilization; and

(5) does not include any drug or other method used to terminate a pregnancy.

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