118TH CONGRESS
1ST SESSION

H. R. _____

To encourage sponsors of oral contraceptive drugs to submit applications for the approval of such drugs as over-the-counter, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mrs. MILLER-MEEKS introduced the following bill; which was referred to the Committee on _____________________

A BILL

To encourage sponsors of oral contraceptive drugs to submit applications for the approval of such drugs as over-the-counter, and for other purposes.

1 Be it enacted by the Senate and House of Representa-
2 tives of the United States of America in Congress assembled,
3 SECTION 1. SHORT TITLE.
4 This Act may be cited as the “Orally Taken Contra-
5 ception Act of 2023” or the “OTC Act of 2023”.

(Original Signature of Member)
SEC. 2. FDA GUIDANCE ON CHANGING MARKETING STATUS
OF CONTRACEPTIVE DRUGS TO OVER-THE-COUNTER.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services acting through 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 au-

thorization, or licensure of oral contraceptive
drugs under the provisions of law specified in
paragraph (1);

(B) the standards used to grant such ap-
proval, marketing authorization, or licensure;

and

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

(4) details the Secretary’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 Secretary of Health and
Human Services, acting through the Commissioner
of Food and Drugs, shall complete a study on con-
sumer comprehension of the labeling of oral contra-
ceptive drugs.

(2) ISSUES TO BE STUDIED.—The study re-
quired by paragraph (1) shall address how the label-
ing 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 indi-
cated.

(3) COMPLETION; PUBLICATION.—The Sec-
retary of Health and Human Services, acting
through 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 fer-
tilization; and
(5) does not include any drug or other method used to terminate a pregnancy.