AMENDMENT NO._____ Calendar No._____

Purpose: To amend the Federal Food, Drug, and Cosmetic Act to provide for expedited approval of certain nonprescription drugs.

IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.

S. 3794

To amend the Federal Food, Drug, and Cosmetic Act to further regulate compounding pharmacies and outsourcing facilities, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. HUSTED

Viz:

At the end, add the following:

TITLE II—EXPEDITED APPROVAL OF NONPRESCRIPTION DRUGS

SEC. 201. EXPEDITED APPROVAL OF CERTAIN NONPRESCRIPTION DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505G (21 U.S.C. 355h) the following:

"SEC. 505H. EXPEDITED APPROVAL OF CERTAIN NON-PRESCRIPTION DRUGS.

''(a) IN GENERAL.—The Secretary shall, at the request of the sponsor of an application submitted under section 505 for nonprescription drug or an application for an Rx-to-nonprescription switch, expedite the development and review of such application if the nonprescription drug or prescription drug, as applicable—

''(1) is intended, alone or in combination with 1 or more other drugs, to treat a chronic disease or condition that is undertreated;

''(2) is a drug no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 505(b); or

''(3) is included on the most recent list published pursuant to subsection (d).

''(b) REQUEST FOR DESIGNATION.—The sponsor of an application described in subsection (a) may request the Secretary to designate the drug as meeting 1 or more of the criteria described in such subsection. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i).

''(c) DESIGNATION.—

''(1) IN GENERAL.—Not later than 90 calendar days after the receipt of a request under subsection (b), the Secretary shall determine whether the drug that is the subject of the request meets 1 or more of the criteria described in subsection (a). If the Secretary finds that the drug meets such criteria, the Secretary shall designate the drug as meeting such criteria and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

''(2) ACTIONS.—The actions to expedite the development and review of an application under paragraph (1) may include, as appropriate—

''(A) holding meetings with the sponsor and the review team throughout the development of the drug;

''(B) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;

''(C) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

"(D) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

"(E) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

"(d) PUBLICATION OF LIST OF POTENTIAL DRUGS FOR RX-TO-NONPRESCRIPTION SWITCH.—

"(1) IN GENERAL.—Not later than 120 days after the date of enactment of the SAFE Drugs Act of 2026, and biennially thereafter, the Secretary, after public notice and a comment period of not less than 30 days, shall publish in the Federal Register a list of prescription drugs that may be promising candidates for an Rx-to-nonprescription switch.

"(2) CONSIDERATIONS.—In publishing a list under paragraph (1), the Secretary shall consider—

"(A) the diseases or conditions a particular prescription drug is intended to treat;

"(B) how long a particular prescription drug has been available in the United States;

"(C) whether a particular prescription drug is available without a prescription in other countries with comparable regulatory schemes; and

"(D) the public health need for a particular prescription drug.

"(3) REQUIREMENT.—In publishing a list under paragraph (1), the Secretary may not exclude a prescription drug based solely on the fact that the disease or condition a particular prescription drug is intended to treat was not previously considered under paragraph (2)(A).

"(e) DEFINITIONS.—In this section:

"(1) NONPRESCRIPTION DRUG APPLICATION.—The term 'nonprescription drug' means a drug that is not subject to section 503(b)(1).

"(2) RX-TO-NONPRESCRIPTION SWITCH.—The term 'Rx-to-nonprescription switch' has the meaning given such term in section 505(b)(7)(E).".

SEC. 202. PILOT PROGRAM FOR INFORMAL ENGAGEMENT ON APPLICATIONS FOR AN RX-TO-NON-PRESCRIPTION SWITCH.

Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall establish a pilot program under which a sponsor planning to submit an application for an Rx-to-non-prescription switch (as defined in subparagraph (E) of section 505(b)(7)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(7)) may engage informally with review staff of the Food and Drug Administration for streamlined, general, non-written feedback based on a generalized description of the issues and without an expectation of submission of a meeting package or specific agreements on meeting topics.

SEC. 203. CONSIDERATION OF SAFETY AND EFFECTIVENESS FOR APPLICATIONS FOR AN RX-TO-NON-PRESCRIPTION SWITCH.

Section 505(b)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(7)) is amended—

(1) in subparagraph (B)(ii)(II), by striking ''subparagraph (A)'' and inserting ''subparagraph (B)'';

(2) by redesignating subparagraphs (A) through (E) as subparagraphs (B) through (F), respectively; and

(3) by inserting before subparagraph (B) (as so redesignated) the following:

''(A) IN GENERAL.—In determining the safety and effectiveness of a drug that is the subject of an application for an Rx-to-non-prescription switch, the Secretary shall consider the benefit-risk profile of such drug, taking into account a comprehensive consideration of the full scope of benefits of making such drug available without a prescription, including public and population health considerations, such as—

''(i) reduction of disease burden;

''(ii) downstream clinical preventive outcomes;

''(iii) the health benefits of potential avoidance of disease progression and associated more advanced medical interventions and care;

''(iv) improvement of quality of life; and

''(v) rational use of health system resources.''.