119TH CONGRESS
1ST SESSION

S. _____

To increase the clarity and predictability of the process for developing applications for Rx-to-nonprescription switches.

IN THE SENATE OF THE UNITED STATES

Mr. HUSTED (for himself and Ms. HASSAN) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To increase the clarity and predictability of the process for developing applications for Rx-to-nonprescription switches.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. INCREASING THE CLARITY AND PREDICTABILITY OF THE PROCESS FOR DEVELOPING APPLICATIONS FOR RX-TO-NONPRESCRIPTION SWITCHES.

(a) IN GENERAL.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(7) RX-TO-NONPRESCRIPTION SWITCHES.—

''(A) MEETINGS.—Any person planning to submit an application for an Rx-to-nonprescription switch may submit to the Secretary a written request for a meeting, for purposes of developing a plan for such application that addresses the potential risks to public health of such switch and the evidence necessary to support such application, including the design of any necessary studies, and the format and content of the planned application. The Secretary may grant such a meeting, as appropriate, consistent with established procedures for granting meetings with, and providing to, applications under this section. Each such meeting shall be documented in meeting minutes.

''(B) GUIDANCE.—

''(i) IN GENERAL.—Not later than 18 months after the date of enactment of this paragraph, the Secretary shall issue guidance to increase the clarity and predictability of the process and standards for approval of applications for nonprescription drugs under this section, including in the case of applications for an Rx-to-nonprescription switch, especially with respect

to prescription drugs with well-established safety profiles for which an applicant may seek approval for nonprescription use.

''(ii) CONTENTS.—The guidance under clause (i) shall—

''(I) describe how published reports in medical literature, any previous finding of safety or effectiveness for the drug under this section, the results of significant human experience with the drug, unpublished studies and other data, and other sources of information may be used to support an application for a nonprescription drug, including in the context of an application for an Rx-to-nonprescription switch;

''(II) set forth procedures for sponsors to request meetings described in subparagraph (A) and document the recommendations made in such meetings;

''(III) describe evidentiary expectations to support approval of an application for a nonprescription drug,

including in the context of an application for an Rx-to-nonprescription switch, including how sponsors can demonstrate that consumers can appropriately self-select and use the drug and comprehend the nonprescription drug label; and

''(IV) provide recommendations for how mechanisms, in addition to the required Drug Facts Label, such as mobile applications and decisions aids, can be incorporated into the information submitted in support of an application for an Rx-to-nonprescription switch.

''(C) PLAN TO ENGAGE WITH STAKEHOLDERS.—Not later than 1 year after the date of enactment of this paragraph, the Secretary shall develop and make publicly available on the website of the Food and Drug Administration a plan to engage stakeholders on steps and factors for application holders and other stakeholders to consider in identifying approved prescription drugs that may be promising can-

didates for applications for an Rx-to-non-prescription switch.

''(D) DEFINITION.—The term 'Rx-to-non-prescription switch' means the approval of an application, or supplemental application, as applicable, submitted under this section by the holder of an approved application for a prescription drug seeking approval to market such drug as a nonprescription drug, including for—

''(i) a full Rx-to-nonprescription switch, under which a drug previously approved for prescription use only is—

''(I) approved for nonprescription use under the same conditions of use as applied to the drug when approved for prescription use; or

''(II) approved for nonprescription use subject to one or more additional conditions for nonprescription use; and

''(ii) a partial Rx-to-nonprescription switch, under which the drug is approved for nonprescription use only under certain conditions of use described in the approved

labeling, while the drug otherwise remains approved for prescription use only.

''(E) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed to—

''(i) supersede or modify the authority of the Secretary under section 505G with respect to the regulation of OTC monograph drugs; or

''(ii) authorize the disclosure by the Secretary of confidential commercial information or trade secrets.''.

(b) GAO REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that evaluates—

(A) the number applications for an Rx-to-nonprescription switch approved during the period beginning on October 1, 2022, and ending on the date of the report;

(B) the number of drugs for which an application for an Rx-to-nonprescription switch

was approved during such period subject to an additional condition for nonprescription use;

(C) among the drugs for which an application for a full or partial Rx-to-nonprescription switch was approved during such period, the average length of time from receipt by the Food and Drug Administration of the application to the approval of such application;

(D) the number of partial Rx-to-nonprescription switch applications approved during such period, and the number of applications for such a partial switch not approved;

(E) any barriers to timely and predictable review of applications for an Rx-to-nonprescription switch;

(F) engagement by the Food and Drug Administration with public stakeholders, including public meetings or additional activities to support review of applications for an Rx-to-nonprescription switch; and

(G) opportunities for collaboration between the Center for Drug Evaluation and Research and the Centers for Medicare & Medicaid Services for the purpose of analyzing health insurance claims data for commonly prescribed drugs

that appear to be suitable for an Rx-to-non-prescription switch.

(2) DEFINITION.—In this subsection, the term ''Rx-to-nonprescription switch'' has the meaning given such term in paragraph (7) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 244(b)), as added by subsection (a).