

119TH CONGRESS
1ST SESSION

S. 2529

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

IN THE SENATE OF THE UNITED STATES

JULY 30, 2025

Mr. HUSTED (for himself and Ms. HASSAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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

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. INCREASING THE CLARITY AND PREDICT-**
4 **ABILITY OF THE PROCESS FOR DEVELOPING**
5 **APPLICATIONS FOR RX-TO-NONPRESCRIP-**
6 **TION SWITCHES.**

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

10 “(7) RX-TO-NONPRESCRIPTION SWITCHES.—

1 “(A) MEETINGS.—Any person planning to
2 submit an application for an Rx-to-nonprescrip-
3 tion switch may submit to the Secretary a writ-
4 ten request for a meeting, for purposes of devel-
5 oping a plan for such application that addresses
6 the potential risks to public health of such
7 switch and the evidence necessary to support
8 such application, including the design of any
9 necessary studies, and the format and content
10 of the planned application. The Secretary may
11 grant such a meeting, as appropriate, consistent
12 with established procedures for granting meet-
13 ings with, and providing to, applications under
14 this section. Each such meeting shall be docu-
15 mented in meeting minutes.

16 “(B) GUIDANCE.—

17 “(i) IN GENERAL.—Not later than 18
18 months after the date of enactment of this
19 paragraph, the Secretary shall issue guid-
20 ance to increase the clarity and predict-
21 ability of the process and standards for ap-
22 proval of applications for nonprescription
23 drugs under this section, including in the
24 case of applications for an Rx-to-non-
25 prescription switch, especially with respect

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

4 “(ii) CONTENTS.—The guidance
5 under clause (i) shall—

6 “(I) describe how published re-
7 ports in medical literature, any pre-
8 vious finding of safety or effectiveness
9 for the drug under this section, the
10 results of significant human experi-
11 ence with the drug, unpublished stud-
12 ies and other data, and other sources
13 of information may be used to support
14 an application for a nonprescription
15 drug, including in the context of an
16 application for an Rx-to-nonprescrip-
17 tion switch;

18 “(II) set forth procedures for
19 sponsors to request meetings de-
20 scribed in subparagraph (A) and doc-
21 ument the recommendations made in
22 such meetings;

23 “(III) describe evidentiary expec-
24 tations to support approval of an ap-
25 plication for a nonprescription drug,

1 including in the context of an applica-
2 tion for an Rx-to-nonprescription
3 switch, including how sponsors can
4 demonstrate that consumers can ap-
5 propriately self-select and use the
6 drug and comprehend the non-
7 prescription drug label; and

8 “(IV) provide recommendations
9 for how mechanisms, in addition to
10 the required Drug Facts Label, such
11 as mobile applications and decisions
12 aids, can be incorporated into the in-
13 formation submitted in support of an
14 application for an Rx-to-nonprescrip-
15 tion switch.

16 “(C) PLAN TO ENGAGE WITH STAKE-
17 HOLDERS.—Not later than 1 year after the
18 date of enactment of this paragraph, the Sec-
19 retary shall develop and make publicly available
20 on the website of the Food and Drug Adminis-
21 tration a plan to engage stakeholders on steps
22 and factors for application holders and other
23 stakeholders to consider in identifying approved
24 prescription drugs that may be promising can-

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

3 “(D) DEFINITION.—The term ‘Rx-to-non-
4 prescription switch’ means the approval of an
5 application, or supplemental application, as ap-
6 plicable, submitted under this section by the
7 holder of an approved application for a pre-
8 scription drug seeking approval to market such
9 drug as a nonprescription drug, including for—

10 “(i) a full Rx-to-nonprescription
11 switch, under which a drug previously ap-
12 proved for prescription use only is—

13 “(I) approved for nonprescription
14 use under the same conditions of use
15 as applied to the drug when approved
16 for prescription use; or

17 “(II) approved for nonprescrip-
18 tion use subject to one or more addi-
19 tional conditions for nonprescription
20 use; and

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

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

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

5 “(i) supersede or modify the authority
6 of the Secretary under section 505G with
7 respect to the regulation of OTC mono-
8 graph drugs; or

9 “(ii) authorize the disclosure by the
10 Secretary of confidential commercial infor-
11 mation or trade secrets.”.

12 (b) GAO REPORT.—

13 (1) IN GENERAL.—Not later than 1 year after
14 the date of enactment of this Act, the Comptroller
15 General of the United States shall submit to the
16 Committee on Health, Education, Labor, and Pen-
17 sions of the Senate and the Committee on Energy
18 and Commerce of the House of Representatives a re-
19 port that evaluates—

20 (A) the number applications for an Rx-to-
21 nonprescription switch approved during the pe-
22 riod beginning on October 1, 2022, and ending
23 on the date of the report;

24 (B) the number of drugs for which an ap-
25 plication for an Rx-to-nonprescription switch

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

3 (C) among the drugs for which an applica-
4 tion for a full or partial Rx-to-nonprescription
5 switch was approved during such period, the av-
6 erage length of time from receipt by the Food
7 and Drug Administration of the application to
8 the approval of such application;

9 (D) the number of partial Rx-to-non-
10 prescription switch applications approved dur-
11 ing such period, and the number of applications
12 for such a partial switch not approved;

13 (E) any barriers to timely and predictable
14 review of applications for an Rx-to-nonprescrip-
15 tion switch;

16 (F) engagement by the Food and Drug
17 Administration with public stakeholders, includ-
18 ing public meetings or additional activities to
19 support review of applications for an Rx-to-non-
20 prescription switch; and

21 (G) opportunities for collaboration between
22 the Center for Drug Evaluation and Research
23 and the Centers for Medicare & Medicaid Serv-
24 ices for the purpose of analyzing health insur-
25 ance claims data for commonly prescribed drugs

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

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

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