

115TH CONGRESS
1ST SESSION

S. 1115

To improve access to prescription drugs.

IN THE SENATE OF THE UNITED STATES

MAY 11, 2017

Ms. COLLINS (for herself, Mrs. MCCASKILL, Mr. COTTON, and Mr. FRANKEN)
introduced the following bill; which was read twice and referred to the
Committee on Health, Education, Labor, and Pensions

A BILL

To improve access to prescription drugs.

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 “Making Pharma-
5 ceutical Markets More Competitive Act”.

1 **TITLE I—REMOVING REGULA-**
2 **TORY BARRIERS TO COMPETI-**
3 **TION**

4 **SEC. 101. IMPROVING ACCESS TO GENERIC DRUGS.**

5 Section 505(j) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 355(j)) is amended by adding at the
7 end the following:

8 “(11)(A) The Secretary shall prioritize the review of,
9 and act within 240 calendar days of the date of the sub-
10 mission of, an original abbreviated new drug application
11 submitted for review under this subsection, or on a supple-
12 ment to such an application, that is for a drug—

13 “(i) for which there are not more than 3 ap-
14 proved drugs listed under paragraph (7), except that
15 the review of an application submitted more than 30
16 months in advance of the last applicable expiration
17 date for a patent for which a certification under
18 paragraph (2)(A)(vii)(III) has been submitted, or of
19 the expiration date for an applicable period of exclu-
20 sivity under this Act, will not be expedited; or

21 “(ii) that has been included on the list under
22 section 506E.

23 “(B) The Secretary shall require the applicant, not
24 later than 60 days prior to the submission of an applica-
25 tion described in subparagraph (A), to provide complete,

1 accurate information regarding facilities involved in manu-
2 facturing processes and testing, including facilities in cor-
3 responding Type II active pharmaceutical ingredients drug
4 master files submitted with an application and sites or or-
5 ganizations involved in bioequivalence and clinical studies
6 used to support the application, in order to make a deter-
7 mination regarding whether an inspection of an establish-
8 ment is necessary.

9 “(C) The Secretary may expedite an inspection or re-
10 inspection under section 704 of an establishment that pro-
11 poses to manufacture a drug described in subparagraph
12 (A).

13 “(D) Nothing in this paragraph shall prevent the Sec-
14 retary from prioritizing the review of other applications
15 as the Secretary determines appropriate.

16 “(12) The Secretary shall provide review status up-
17 dates to applicants regarding applications under this sub-
18 section, as appropriate, including when the application is
19 awaiting final regulatory action by the office charged with
20 review.

21 “(13) The Secretary shall publish on the Internet
22 website of the Food and Drug Administration a list of all
23 drugs approved under subsection (b) for which all patents
24 and periods of exclusivity under this Act have expired.
25 Such list shall be updated at least once every 180 days.”.

1 **SEC. 102. REPORTING ON PENDING GENERIC DRUG APPLI-**
2 **CATIONS, PRIORITY REVIEW APPLICATIONS,**
3 **AND INSPECTIONS.**

4 (a) IN GENERAL.—Not later than 180 calendar days
5 after the date of enactment of this Act, and quarterly
6 thereafter until October 1, 2022, the Secretary of Health
7 and Human Services (referred to in this section as the
8 “Secretary”) shall post on the Internet website of the
9 Food and Drug Administration a report that provides—

10 (1) the number of applications filed under sec-
11 tion 505(j) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 355(j)) awaiting action by the appli-
13 cant, including such applications that were filed
14 prior to October 1, 2014;

15 (2) the number of applications filed under sec-
16 tion 505(j) of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 355(j)) awaiting action by the Sec-
18 retary, including such applications that were filed
19 prior to October 1, 2014;

20 (3) the number of applications filed under sec-
21 tion 505(j) of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 355(j)) and prior approval supple-
23 ments withdrawn in each month covered by the re-
24 port;

1 (4) the mean and median approval and ten-
2 tative approval times for applications covered by the
3 report;

4 (5) the number of applications described in
5 paragraphs (1), (2), and (3) that are subject to pri-
6 ority review; and

7 (6) the number of such applications on which
8 the Secretary has taken action pursuant to section
9 506H(b) of the Federal Food, Drug, and Cosmetic
10 Act, as added by section 101.

11 (b) ANNUAL REPORT ON PRIORITY REVIEW APPLI-
12 CATIONS.—

13 (1) IN GENERAL.—The Secretary shall submit
14 to the Committee on Health, Education, Labor, and
15 Pensions and the Special Committee on Aging of the
16 Senate and the Committee on Energy and Com-
17 merce of the House of Representatives an annual re-
18 port, not later than March 31 of each year, on the
19 following:

20 (A) The number of applications filed under
21 section 505(j) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 355(j)) that are sub-
23 ject to priority review during the most recent
24 calendar year and are awaiting action by the
25 applicant.

1 (B) The number of applications filed under
2 section 505(j) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355(j)) that are sub-
4 ject to priority review during the most recent
5 calendar year and are awaiting action by the
6 Secretary.

7 (C) The number of applications filed under
8 section 505(j) of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 355(j)) that are sub-
10 ject to priority review during the most recent
11 calendar year and have been approved by the
12 Secretary.

13 (D) For each of subparagraphs (A)
14 through (C), the number of such applications—

15 (i) for which there are not more than
16 3 approved drugs listed under section
17 505(j)(7) of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 355(j)(7)); and

19 (ii) the number of such applications
20 that are for a drug on the drug shortage
21 list under section 506E of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C.
23 356e).

24 (c) ANNUAL REPORT ON INSPECTIONS.—Not later
25 than March 1 of each year, the Secretary shall post on

1 the Internet website of the Food and Drug Administra-
 2 tion—

3 (1) the average and median amount of time,
 4 following a request by staff of the Food and Drug
 5 Administration reviewing an application or report
 6 submitted under an applicable section described in
 7 subparagraph (A), (B), or (C), to schedule and com-
 8 plete inspections of facilities necessary for—

9 (A) approval of a drug under section 505
 10 of the Federal Food, Drug, and Cosmetic Act
 11 (21 U.S.C. 355);

12 (B) approval of a device under section 515
 13 of such Act (21 U.S.C. 360e); and

14 (C) clearance of a device under section
 15 510(k) of such Act (21 U.S.C. 360(k)); and

16 (2) the average and median amount of time to
 17 schedule and complete for-cause inspections of facili-
 18 ties of drugs and devices.

19 **TITLE II—INCENTIVIZING** 20 **COMPETITION**

21 **SEC. 201. EXPEDITING GENERIC COMPETITION.**

22 Chapter V of the Federal Food, Drug, and Cosmetic
 23 Act (21 U.S.C. 351 et seq.) is amended by inserting after
 24 section 506G the following:

1 **“SEC. 506H. EXPEDITING GENERIC DRUG DEVELOPMENT.**

2 “(a) IN GENERAL.—The Secretary shall, at the re-
3 quest of an applicant, expedite the development and review
4 of an application under subsection (j) of section 505 for
5 a drug—

6 “(1) for which there are not more than 3 ap-
7 proved drug products listed under section 505(j)(7);
8 or

9 “(2) that is included on the list under section
10 506E.

11 “(b) REQUEST FROM SPONSORS.—A request to expe-
12 dite the development and review of an application under
13 subsection (a) shall be submitted by the applicant prior
14 to the submission of such application.

15 “(c) OTHER APPLICATIONS.—Nothing in this section
16 shall prevent the Secretary from expediting the develop-
17 ment and review of other applications as the Secretary de-
18 termines appropriate.

19 “(d) ADDITIONAL COMMUNICATION.—The Secretary
20 shall take such actions as are appropriate to expedite the
21 development and review of the application for approval of
22 a drug described in subsection (a), including, as appro-
23 priate—

24 “(1) holding meetings with the sponsor and the
25 review team throughout the development of the drug
26 prior to submission of the application;

1 “(2) providing timely advice to, and interactive
2 communication with, the sponsor regarding the de-
3 velopment of the application to ensure that the col-
4 lection of nonclinical and clinical data necessary for
5 approval is as efficient as practicable;

6 “(3) in the case of a complex product, assigning
7 a cross-disciplinary project lead for the review team
8 to facilitate an efficient review of the development
9 program and application, including manufacturing
10 inspections; and

11 “(4) in the case of a complex product, including
12 drug-device combinations, involving senior managers
13 and experienced review staff, as appropriate, in a
14 collaborative, cross-disciplinary review.

15 “(e) REPORTING REQUIREMENT.—A sponsor of a
16 drug expedited under this section shall report to the Sec-
17 retary, one year following approval of an application under
18 section 505(j), on whether the approved drug has been
19 marketed in interstate commerce since approval.”.

20 **SEC. 202. LIST OF GENERIC DRUGS WITH LIMITED COM-**
21 **PETITION.**

22 Chapter V of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 351 et seq.) is amended by inserting after
24 section 506H, as added by section 201, the following:

1 **“SEC. 506I. DRUG LISTING.**

2 “(a) REMOVAL, WITHDRAWAL, OR TRANSFER.—The
3 holder of an application approved under subsection (b) or
4 (j) of section 505 shall notify the Secretary within 180
5 days of removing the drug that is the subject of such ap-
6 plication from interstate commerce, withdrawing such ap-
7 proved application, or transferring such approved applica-
8 tion, and a reason for such removal, withdrawal, or trans-
9 fer. If compliance with this subsection within such 180-
10 day period is not practicable, then the holder shall comply
11 as soon as practicable. The Secretary shall cross-reference
12 information listed pursuant to section 506C where applica-
13 ble to avoid duplicative reporting. Notification to the Sec-
14 retary by a manufacturer in accordance with section
15 506C(a) shall be deemed to be compliance with this sec-
16 tion.

17 “(b) DRUGS WITH LIMITED COMPETITION.—

18 “(1) INFORMATION.—The Secretary shall—

19 “(A) maintain information with respect to
20 applications approved under section 505(j); and

21 “(B) publish on the Internet website of the
22 Food and Drug Administration such informa-
23 tion under subparagraph (A) with respect to
24 drugs for which there are three or fewer appli-
25 cation holders; and

1 “(C) update the information published pur-
2 suant to subparagraph (B) every 180 days.

3 “(2) CONTENTS.—The public information main-
4 tained and published under paragraph (1)(B) shall
5 include—

6 “(A) the name of the drug, name of the
7 holder of the approved application, and the
8 marketing status for each drug; and

9 “(B) an indication of whether the Sec-
10 retary considers the drug to be for the treat-
11 ment or prevention of a serious disease or med-
12 ical condition, for which there is no alternative
13 drug that is judged by medical professionals to
14 be an adequate substitute available in adequate
15 supply.

16 “(c) PUBLIC HEALTH EXCEPTION.—The Secretary
17 may choose not to make information collected under this
18 section publicly available if the Secretary determines that
19 disclosure of such information would adversely affect the
20 public health.

21 “(d) NOTIFICATION.—When the Secretary first pub-
22 lishes the information under subsection (b), the Secretary
23 shall notify relevant Federal agencies, including the Cen-
24 ters for Medicare & Medicaid Services and the Federal

1 Trade Commission, that the information has been pub-
 2 lished and will be updated regularly.”.

3 **SEC. 203. SUITABILITY PETITIONS.**

4 (a) IN GENERAL.—It is the sense of the Senate that
 5 the Food and Drug Administration shall meet the require-
 6 ment under section 505(j)(2)(C) of the Federal Food,
 7 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(C)) and sec-
 8 tion 314.93(e) of title 21, Code of Federal Regulations,
 9 of responding to suitability petitions within 90 days of
 10 submission.

11 (b) REPORT.—The Secretary of Health and Human
 12 Services shall include in the annual reports under section
 13 102(b)—

14 (1) the number of pending petitions under sec-
 15 tion 505(j)(2)(C) of the Federal Food, Drug, and
 16 Cosmetic Act (21 U.S.C. 355(j)(5)(C)); and

17 (2) the number of such petitions pending a sub-
 18 stantive response for more than 180 days from the
 19 date of receipt.

20 **SEC. 204. INSPECTIONS.**

21 Section 505(j) of the Federal Food, Drug, and Cos-
 22 metic Act (21 U.S.C. 355(j)), as amended by section 101,
 23 is further amended by adding at the end the following:

24 “(14) If the Secretary issues feedback pursuant to
 25 section 704(b)(2) with respect to information submitted

1 in response to a report under section 704(b)(1), and a re-
2 port that was issued under section 704(b)(1) is the only
3 obstacle to approval of an application under this sub-
4 section or the Secretary determines that the public health
5 benefit of approving an application under this subsection
6 outweighs any risk to public health, the Secretary shall,
7 within 45 days of notification by the applicant that nec-
8 essary changes have been made to the establishment to
9 address any findings or deficiencies identified previously
10 by the Secretary—

11 “(A) re-inspect the establishment with respect
12 to which the report was issued; or

13 “(B) make a determination regarding the re-
14 sponse to such report and review of such applica-
15 tion.”.

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