

115TH CONGRESS
1ST SESSION

H. R. 2562

To improve access to prescription drugs.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2017

Mr. KELLY of Pennsylvania introduced the following bill; which was referred
to the Committee on Energy and Commerce

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”.

6 **TITLE I—REMOVING REGU-**
7 **LATORY BARRIERS TO COM-**
8 **PETITION**

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

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

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

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

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

16 “(B) The Secretary shall require the applicant, not
17 later than 60 days prior to the submission of an applica-
18 tion described in subparagraph (A), to provide complete,
19 accurate information regarding facilities involved in manu-
20 facturing processes and testing, including facilities in cor-
21 responding Type II active pharmaceutical ingredients drug
22 master files submitted with an application and sites or or-
23 ganizations involved in bioequivalence and clinical studies
24 used to support the application, in order to make a deter-

1 mination regarding whether an inspection of an establish-
2 ment is necessary.

3 “(C) The Secretary may expedite an inspection or re-
4 inspection under section 704 of an establishment that pro-
5 poses to manufacture a drug described in subparagraph
6 (A).

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

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

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

20 **SEC. 102. REPORTING ON PENDING GENERIC DRUG APPLI-**
21 **CATIONS, PRIORITY REVIEW APPLICATIONS,**
22 **AND INSPECTIONS.**

23 (a) IN GENERAL.—Not later than 180 calendar days
24 after the date of enactment of this Act, and quarterly
25 thereafter until October 1, 2022, the Secretary of Health

1 and Human Services (referred to in this section as the
2 “Secretary”) shall post on the Internet website of the
3 Food and Drug Administration a report that provides—

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

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

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

19 (4) the mean and median approval and ten-
20 tative approval times for applications covered by the
21 report;

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

1 (6) the number of such applications on which
2 the Secretary has taken action pursuant to section
3 506H(b) of the Federal Food, Drug, and Cosmetic
4 Act, as added by section 101.

5 (b) ANNUAL REPORT ON PRIORITY REVIEW APPLI-
6 CATIONS.—

7 (1) IN GENERAL.—The Secretary shall submit
8 to the Committee on Health, Education, Labor, and
9 Pensions and the Special Committee on Aging of the
10 Senate and the Committee on Energy and Com-
11 merce of the House of Representatives an annual re-
12 port, not later than March 31 of each year, on the
13 following:

14 (A) The number of applications filed under
15 section 505(j) of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 355(j)) that are sub-
17 ject to priority review during the most recent
18 calendar year and are awaiting action by the
19 applicant.

20 (B) 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 Secretary.

1 (C) 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 have been approved by the
6 Secretary.

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

9 (i) for which there are not more than
10 3 approved drugs listed under section
11 505(j)(7) of the Federal Food, Drug, and
12 Cosmetic Act (21 U.S.C. 355(j)(7)); and

13 (ii) the number of such applications
14 that are for a drug on the drug shortage
15 list under section 506E of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C.
17 356e).

18 (c) ANNUAL REPORT ON INSPECTIONS.—Not later
19 than March 1 of each year, the Secretary shall post on
20 the Internet website of the Food and Drug Administra-
21 tion—

22 (1) the average and median amount of time,
23 following a request by staff of the Food and Drug
24 Administration reviewing an application or report
25 submitted under an applicable section described in

1 subparagraph (A), (B), or (C), to schedule and com-
2 plete inspections of facilities necessary for—

3 (A) approval of a drug under section 505
4 of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 355);

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

8 (C) clearance of a device under section
9 510(k) of such Act (21 U.S.C. 360(k)); and

10 (2) the average and median amount of time to
11 schedule and complete for-cause inspections of facili-
12 ties of drugs and devices.

13 **TITLE II—INCENTIVIZING** 14 **COMPETITION**

15 **SEC. 201. EXPEDITING GENERIC COMPETITION.**

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

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

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

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

4 “(2) that is included on the list under section
5 506E.

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

10 “(c) OTHER APPLICATIONS.—Nothing in this section
11 shall prevent the Secretary from expediting the develop-
12 ment and review of other applications as the Secretary de-
13 termines appropriate.

14 “(d) ADDITIONAL COMMUNICATION.—The Secretary
15 shall take such actions as are appropriate to expedite the
16 development and review of the application for approval of
17 a drug described in subsection (a), including, as appro-
18 priate—

19 “(1) holding meetings with the sponsor and the
20 review team throughout the development of the drug
21 prior to submission of the application;

22 “(2) providing timely advice to, and interactive
23 communication with, the sponsor regarding the de-
24 velopment of the application to ensure that the col-

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

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

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

17 SEC. 202. LIST OF GENERIC DRUGS WITH LIMITED COM-
18 PETITION.

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

22 **“SEC. 506I. DRUG LISTING.**

23 “(a) REMOVAL, WITHDRAWAL, OR TRANSFER.—The
24 holder of an application approved under subsection (b) or
25 (j) of section 505 shall notify the Secretary within 180

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

13 “(b) DRUGS WITH LIMITED COMPETITION.—

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

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

17 “(B) publish on the Internet website of the
18 Food and Drug Administration such informa-
19 tion under subparagraph (A) with respect to
20 drugs for which there are 3 or fewer application
21 holders; and

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

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

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

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

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

19 “(d) NOTIFICATION.—When the Secretary first pub-
20 lishes the information under subsection (b), the Secretary
21 shall notify relevant Federal agencies, including the Cen-
22 ters for Medicare & Medicaid Services and the Federal
23 Trade Commission, that the information has been pub-
24 lished and will be updated regularly.”.

1 **SEC. 203. SUITABILITY PETITIONS.**

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

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

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

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

18 **SEC. 204. INSPECTIONS.**

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

22 “(14) If the Secretary issues feedback pursuant to
23 section 704(b)(2) with respect to information submitted
24 in response to a report under section 704(b)(1), and a re-
25 port that was issued under section 704(b)(1) is the only
26 obstacle to approval of an application under this sub-

1 section or the Secretary determines that the public health
2 benefit of approving an application under this subsection
3 outweighs any risk to public health, the Secretary shall,
4 within 45 days of notification by the applicant that nec-
5 essary changes have been made to the establishment to
6 address any findings or deficiencies identified previously
7 by the Secretary—

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

10 “(B) make a determination regarding the re-
11 sponse to such report and review of such applica-
12 tion.”.

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