

112TH CONGRESS  
2D SESSION

# H. R. 4332

To amend section 505(j) of the Federal Food, Drug, and Cosmetic Act to extend the period for a first applicant, with respect to a generic drug, to obtain tentative approval without forfeiting the 180-day exclusivity period, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 29, 2012

Mr. PALLONE (for himself and Mr. GUTHRIE) introduced the following bill;  
which was referred to the Committee on Energy and Commerce

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## A BILL

To amend section 505(j) of the Federal Food, Drug, and Cosmetic Act to extend the period for a first applicant, with respect to a generic drug, to obtain tentative approval without forfeiting the 180-day exclusivity period, and for other purposes.

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 “Generic Drug Applica-  
5 tion Review Fairness Act of 2012”.

1 **SEC. 2. EXTENSION OF PERIOD FOR FIRST APPLICANT TO**  
2 **OBTAIN TENTATIVE APPROVAL WITHOUT**  
3 **FORFEITING 180-DAY EXCLUSIVITY PERIOD.**

4 (a) EXTENSION OF PERIOD.—

5 (1) IN GENERAL.—Subclause (IV) of section  
6 505(j)(5)(D)(i) of the Federal Food, Drug, and Cos-  
7 metic Act (21 U.S.C. 355(j)(5)(D)(i)) is amended to  
8 read as follows:

9 “(IV) FAILURE TO OBTAIN TEN-  
10 TATIVE APPROVAL.—The first appli-  
11 cant fails to obtain tentative approval  
12 of the application within 60 months  
13 after the date on which—

14 “(aa) the application is filed  
15 and initially contains a certifi-  
16 cation described in paragraph  
17 (2)(A)(vii)(IV), or

18 “(bb) the application is  
19 amended to first contain such a  
20 certification,

21 unless the failure is caused by a  
22 change in or a review of the require-  
23 ments for approval of the application  
24 imposed after the date on which the  
25 application is so filed or amended.”.

26 (2) APPLICABILITY.—

1 (A) IN GENERAL.—Subject to subsection  
2 (b), the amendment made by paragraph (1) ap-  
3 plies—

4 (i) only with respect to an application  
5 that is filed under section 505(j) of the  
6 Federal Food, Drug, and Cosmetic Act (21  
7 U.S.C. 355(j)) on or after the day that is  
8 30 months prior to the date of the enact-  
9 ment of this Act; and

10 (ii) only if no certification under para-  
11 graph (2)(A)(vii)(IV) of such section  
12 505(j) was made before such day with re-  
13 spect to the listed drug (as such term is  
14 used in such section 505(j)).

15 (B) CERTAIN APPLICATIONS.—If an appli-  
16 cation was filed under section 505(j) of the  
17 Federal Food, Drug, and Cosmetic Act (21  
18 U.S.C. 355(j)) prior to the day specified in sub-  
19 paragraph (A)(i) and, on such day, contained a  
20 certification described in paragraph  
21 (2)(A)(vii)(IV), the application shall be subject  
22 to paragraph (5)(D)(i)(IV) of such section  
23 505(j) as in effect on the day before the date  
24 of the enactment of this Act.

1 (b) INCREMENTAL REDUCTION OF EXTENDED PE-  
2 RIOD.—

3 (1) PERIOD DURATION.—

4 (A) Effective on October 1, 2013, sub-  
5 clause (IV) of section 505(j)(5)(D)(i) of the  
6 Federal Food, Drug, and Cosmetic Act (21  
7 U.S.C. 355(j)(5)(D)(i)), as amended by sub-  
8 section (a)(1), is amended by striking “60  
9 months” and inserting “54 months”.

10 (B) Effective on October 1, 2014, sub-  
11 clause (IV) of section 505(j)(5)(D)(i) of the  
12 Federal Food, Drug, and Cosmetic Act (21  
13 U.S.C. 355(j)(5)(D)(i)), as amended by sub-  
14 paragraph (A), is amended by striking “54  
15 months” and inserting “48 months”.

16 (C) Effective on October 1, 2015, sub-  
17 clause (IV) of section 505(j)(5)(D)(i) of the  
18 Federal Food, Drug, and Cosmetic Act (21  
19 U.S.C. 355(j)(5)(D)(i)), as amended by sub-  
20 paragraph (B), is amended by striking “48  
21 months” and inserting “42 months”.

22 (D) Effective on October 1, 2016, sub-  
23 clause (IV) of section 505(j)(5)(D)(i) of the  
24 Federal Food, Drug, and Cosmetic Act (21  
25 U.S.C. 355(j)(5)(D)(i)), as amended by sub-

1 paragraph (C), is amended by striking “42  
2 months” and inserting “36 months”.

3 (E) Effective on October 1, 2017, sub-  
4 clause (IV) of section 505(j)(5)(D)(i) of the  
5 Federal Food, Drug, and Cosmetic Act (21  
6 U.S.C. 355(j)(5)(D)(i)), as amended by sub-  
7 paragraph (D), is amended by striking “36  
8 months” and inserting “30 months”.

9 (2) APPLICABILITY.—

10 (A) The amendments made by subpara-  
11 graphs (A), (B), (C), and (D) of paragraph (1)  
12 apply only with respect to an application under  
13 section 505(j) of the Federal Food, Drug, and  
14 Cosmetic Act (21 U.S.C. 355(j)) that—

15 (i) is filed and initially contains a cer-  
16 tification described in paragraph  
17 (2)(A)(vii)(IV) during the period of one  
18 fiscal year beginning on the effective date  
19 of the respective amendment; or

20 (ii) is amended to initially contain  
21 such a certification during such period.

22 (B) The amendment made by paragraph  
23 (1)(E) applies only with respect to an applica-  
24 tion under section 505(j) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355(j))  
2 that—

3 (i) is filed and initially contains a cer-  
4 tification described in paragraph  
5 (2)(A)(vii)(IV) on or after October 1,  
6 2017; or

7 (ii) is amended to initially contain  
8 such a certification on or after October 1,  
9 2017.

10 (c) CONFORMING AMENDMENT.—Subparagraph (G)  
11 of section 505(q)(1) of the Federal Food, Drug, and Cos-  
12 metic Act (21 U.S.C. 355(q)(1)) is amended by striking  
13 “the 30-month period” and inserting “the period”.

14 **SEC. 3. MAINTENANCE OF OFFICE OF GENERIC DRUGS AT**  
15 **CDER; REPORTING.**

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

19 “(11) OFFICE OF GENERIC DRUGS.—

20 “(A) OFFICE.—The Secretary shall main-  
21 tain the Office of Generic Drugs as a separate  
22 office within the Center for Drug Evaluation  
23 and Research of the Food and Drug Adminis-  
24 tration.

1           “(B) REPORTING.—The Director of the  
2           Office of Generic Drugs shall report directly to  
3           the Director of the Center for Drug Evaluation  
4           and Research.”.

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