

114TH CONGRESS
1ST SESSION

H. R. 1353

To amend the Federal Food, Drug, and Cosmetic Act to extend the period of exclusivity with respect to certain drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 2015

Mr. BILIRAKIS (for himself, Mr. CONNOLLY, Mr. ISRAEL, and Mr. GRIFFITH) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to extend the period of exclusivity with respect to certain drugs, 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 “Promoting Access for
5 Treatments Ideal in Enhancing New Therapies Act of
6 2015”, or the “PATIENT Act of 2015”.

1 **SEC. 2. EXTENDED EXCLUSIVITY PERIOD FOR CERTAIN**
2 **NEW DRUG APPLICATIONS AND ABBRE-**
3 **VIATED NEW DRUG APPLICATIONS.**

4 (a) NEW DRUG APPLICATIONS.—Section
5 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 355(c)(3)(E)) is amended by adding at
7 the end the following new clause:

8 “(vi) With respect to an application described
9 in clause (iii) or a supplement to an application de-
10 scribed in clause (iv), the three-year period specified
11 in such clause shall be extended for an additional
12 24-month period if the person submitting such appli-
13 cation or supplement provides documentation to the
14 Secretary demonstrating that—

15 “(I) the new clinical investigations essen-
16 tial to the approval of the application or supple-
17 ment and conducted or sponsored by the person
18 submitting the application or supplement sup-
19 port the approval of a new indication or use for
20 the drug that is the subject of the application
21 or supplement; or

22 “(II) the drug that is the subject of the
23 application or supplement has been reformu-
24 lated or redesigned so that the drug can reason-
25 ably (as determined by the Secretary in con-

1 sultation with the person submitting such appli-
2 cation or supplement) be expected—

3 “(aa) to promote greater patient ad-
4 herence to an approved treatment regime
5 relative to the previously approved formu-
6 lation or design of the drug;

7 “(bb) to reduce the public-health risks
8 associated with the drug relative to the
9 previously approved formulation or design
10 of the drug;

11 “(cc) to reduce the manner or extent
12 of side effects or adverse events associated
13 with the previously approved formulation
14 or design of the drug;

15 “(dd) to provide systemic benefits to
16 the health-care system relative to the pre-
17 viously approved formulation or design of
18 the drug; or

19 “(ee) to provide other patient benefits
20 that are comparable to the benefits de-
21 scribed in items (aa) through (dd).”.

22 (b) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
23 tion 505(j)(5)(F) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 355(j)(5)(F)) is amended by adding
25 at the end the following new clause:

1 “(vi) With respect to an application described in
2 clause (iii) or a supplement to an application described
3 in clause (iv), the three-year period specified in such
4 clause shall be extended for an additional 24-month period
5 if the person submitting such application or supplement
6 provides documentation to the Secretary demonstrating
7 that—

8 “(I) the new clinical investigations essential to
9 the approval of the application or supplement and
10 conducted or sponsored by the person submitting the
11 application or supplement support the approval of a
12 new indication or use for the drug that is the subject
13 of the application or supplement; or

14 “(II) the drug that is the subject of the applica-
15 tion or supplement has been reformulated or rede-
16 signed so that the drug may reasonably (as deter-
17 mined by the Secretary in consultation with the per-
18 son submitting such application or supplement) be
19 expected—

20 “(aa) to promote greater patient adherence
21 to an approved treatment regime relative to the
22 previously approved formulation or design of
23 the drug;

1 “(bb) to reduce the public-health risks as-
2 sociated with the drug relative to the previously
3 approved formulation or design of the drug;

4 “(cc) to reduce the manner or extent of
5 side effects or adverse events associated with
6 the previously approved formulation or design
7 of the drug;

8 “(dd) to provide systemic benefits to the
9 health-care system relative to the previously ap-
10 proved formulation or design of the drug; or

11 “(ee) to provide other patient benefits that
12 are comparable to the benefits described in
13 items (aa) through (dd).”.

14 (c) REGULATIONS.—Not later than 180 days after
15 the date of the enactment of this Act, the Secretary of
16 Health and Human Services shall promulgate final regula-
17 tions to carry out the amendments made by this section,
18 including regulations establishing a process under which
19 the Secretary consults with persons who claim eligibility
20 for the extension provided by clause (vi) of subsection
21 (c)(3)(E) or (j)(5)(F) of section 505 of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 355) (as added by
23 subsections (a) and (b)) regarding how the drug that is
24 the subject of such a claim may reasonably be expected

- 1 to provide a benefit described in item (aa), (bb), (cc), (dd),
- 2 or (ee) of clause (vi)(II) of each such subsection.

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