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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Promoting Access for Treatments Ideal in Enhancing New Therapies Act of 2015'', or the ''PATIENT Act of 2015''.

SEC. 2. EXTENDED EXCLUSIVITY PERIOD FOR CERTAIN NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.

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

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

''(I) the new clinical investigations essential to the approval of the application or supplement and conducted or sponsored by the person submitting the application or supplement support the approval of a new indication or use for the drug that is the subject of the application or supplement; or

''(II) the drug that is the subject of the application or supplement has been reformulated or redesigned so that the drug can reasonably (as determined by the Secretary in con-

sultation with the person submitting such application or supplement) be expected—

"(aa) to promote greater patient adherence to an approved treatment regime relative to the previously approved formulation or design of the drug;

"(bb) to reduce the public-health risks associated with the drug relative to the previously approved formulation or design of the drug;

"(cc) to reduce the manner or extent of side effects or adverse events associated with the previously approved formulation or design of the drug;

"(dd) to provide systemic benefits to the health-care system relative to the previously approved formulation or design of the drug; or

"(ee) to provide other patient benefits that are comparable to the benefits described in items (aa) through (dd).".

(b) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(F)) is amended by adding at the end the following new clause:

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

''(I) the new clinical investigations essential to the approval of the application or supplement and conducted or sponsored by the person submitting the application or supplement support the approval of a new indication or use for the drug that is the subject of the application or supplement; or

''(II) the drug that is the subject of the application or supplement has been reformulated or redesigned so that the drug may reasonably (as determined by the Secretary in consultation with the person submitting such application or supplement) be expected—

''(aa) to promote greater patient adherence to an approved treatment regime relative to the previously approved formulation or design of the drug;

"(bb) to reduce the public-health risks associated with the drug relative to the previously approved formulation or design of the drug;

"(cc) to reduce the manner or extent of side effects or adverse events associated with the previously approved formulation or design of the drug;

"(dd) to provide systemic benefits to the health-care system relative to the previously approved formulation or design of the drug; or

"(ee) to provide other patient benefits that are comparable to the benefits described in items (aa) through (dd).".

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

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

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