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113TH CONGRESS
1ST SESSION

H. R. 2985

To amend section 505 of the Federal Food, Drug, and Cosmetic Act to provide incentives for the development of new combination drugs.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2013

Mr. CHAFFETZ (for himself, Mr. COBLE, and Mr. SALMON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend section 505 of the Federal Food, Drug, and Cosmetic Act to provide incentives for the development of new combination drugs.

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 ''Combination Drug Development Incentive Act of 2013''.

SEC. 2. APPLICABILITY TO COMBINATION DRUGS SUBMITTED UNDER A NEW DRUG APPLICATION.

(a) IN GENERAL.—Clause (ii) of section 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E)(ii)) is amended—

(1) by striking ''(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b),'' and inserting ''(ii)(I) If an application submitted under subsection (b) for a drug, and described in subclause (II) or (III),''; and

(2) by adding at the end the following:

''(II) An application is described in this subclause if no active ingredient (including any ester or salt of the active ingredient) of the drug for which the application has been submitted has been approved in any other application under subsection (b).

''(III) An application is described in this subclause if—

''(aa) the application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant;

''(bb) the application is for a drug which contains a combination of active ingredients; and

''(cc) no such combination of active ingredients has been approved in any other application under subsection (b).''.

(b) APPLICABILITY.—Subclause (I) of section 505(c)(3)(E)(ii) of the Federal Food, Drug, and Cosmetic Act, as designated by subsection (a)(1), is amended by striking ''is approved after the date of the enactment of this clause'' and inserting ''is approved after January 1, 2014, in the case of an application described in subclause (II) or subclause (III)''.

(c) CONFORMING AMENDMENT.—Clause (iii) of section 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E)) is amended by striking ''If'' and inserting ''Except as provided in clause (ii), if''.

SEC. 3. APPLICABILITY TO COMBINATION DRUGS SUBMITTED UNDER AN ABBREVIATED NEW DRUG APPLICATION.

(a) IN GENERAL.—Clause (ii) of section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(F)) is amended—

(1) by striking ''(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application

under subsection (b),'' and inserting ''(ii)(I) If an application submitted under subsection (b) for a drug, and described in subclause (II) or (III),''; and

(2) by adding at the end the following:

''(II) An application is described in this subclause if no active ingredient (including any ester or salt of the active ingredient) of the drug for which the application has been submitted has been approved in any other application under subsection (b).

''(III) An application is described in this subclause if—

''(aa) the application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant;

''(bb) the application is for a drug which contains a combination of active ingredients; and

''(cc) no such combination of active ingredients has been approved in any other application under subsection (b).''.

(b) APPLICABILITY.—Subclause (I) of section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act, as designated by subsection (a)(1), is amended by striking ''is approved after the date of the enactment of this subsection'' and inserting ''is approved after January

1, 2014, in the case of an application described in subclause (II) or subclause (III)''.

(c) CONFORMING AMENDMENT.—Clause (iii) of section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(F)) is amended by striking ''If'' and inserting ''Except as provided in clause (ii), if''.

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