

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.

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## 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.

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 “Combination Drug De-  
5       velopment Incentive Act of 2013”.

6       **SEC. 2. APPLICABILITY TO COMBINATION DRUGS SUB-**  
7       **MITTED UNDER A NEW DRUG APPLICATION.**

8       (a) IN GENERAL.—Clause (ii) of section 505(c)(3)(E)  
9       of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
10       355(c)(3)(E)(ii)) is amended—

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

8           (2) by adding at the end the following:

9           “(II) An application is described in this sub-  
10          clause if no active ingredient (including any ester or  
11          salt of the active ingredient) of the drug for which  
12          the application has been submitted has been ap-  
13          proved in any other application under subsection (b).

14          “(III) An application is described in this sub-  
15          clause if—

16                 “(aa) the application contains reports of  
17                 new clinical investigations (other than bio-  
18                 availability studies) essential to the approval of  
19                 the application and conducted or sponsored by  
20                 the applicant;

21                 “(bb) the application is for a drug which  
22                 contains a combination of active ingredients;  
23                 and

1           “(cc) no such combination of active ingre-  
2           dients has been approved in any other applica-  
3           tion under subsection (b).”.

4           (b) **APPLICABILITY.**—Subclause (I) of section  
5 505(c)(3)(E)(ii) of the Federal Food, Drug, and Cosmetic  
6 Act, as designated by subsection (a)(1), is amended by  
7 striking “is approved after the date of the enactment of  
8 this clause” and inserting “is approved after January 1,  
9 2014, in the case of an application described in subclause  
10 (II) or subclause (III)”.

11          (c) **CONFORMING AMENDMENT.**—Clause (iii) of sec-  
12 tion 505(c)(3)(E) of the Federal Food, Drug, and Cos-  
13 metic Act (21 U.S.C. 355(c)(3)(E)) is amended by strik-  
14 ing “If” and inserting “Except as provided in clause (ii),  
15 if”.

16 **SEC. 3. APPLICABILITY TO COMBINATION DRUGS SUB-**  
17 **MITTED UNDER AN ABBREVIATED NEW DRUG**  
18 **APPLICATION.**

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

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

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

4 (2) by adding at the end the following:

5 “(II) An application is described in this subclause if  
6 no active ingredient (including any ester or salt of the ac-  
7 tive ingredient) of the drug for which the application has  
8 been submitted has been approved in any other application  
9 under subsection (b).

10 “(III) An application is described in this subclause  
11 if—

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

16 “(bb) the application is for a drug which con-  
17 tains a combination of active ingredients; and

18 “(cc) no such combination of active ingredients  
19 has been approved in any other application under  
20 subsection (b).”.

21 (b) APPLICABILITY.—Subclause (I) of section  
22 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic  
23 Act, as designated by subsection (a)(1), is amended by  
24 striking “is approved after the date of the enactment of  
25 this subsection” and inserting “is approved after January

1 1, 2014, in the case of an application described in sub-  
2 clause (II) or subclause (III)”.

3 (c) CONFORMING AMENDMENT.—Clause (iii) of sec-  
4 tion 505(j)(5)(F) of the Federal Food, Drug, and Cos-  
5 metic Act (21 U.S.C. 355(j)(5)(F)) is amended by striking  
6 “If” and inserting “Except as provided in clause (ii), if”.

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