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(Original Signature of Member)

112TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

To make corrections with respect to Food and Drug Administration user fees.

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IN THE HOUSE OF REPRESENTATIVES

Mr. UPTON (for himself and Mr. WAXMAN) introduced the following bill;  
which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To make corrections with respect to Food and Drug Administration user fees.

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 “FDA User Fee Correc-  
5 tions Act of 2012”.

6 **SEC. 2. CORRECTIONS TO FDA USER FEES.**

7 (a) Section 502(aa) of the Federal Food, Drug, and  
8 Cosmetic Act (21 U.S.C. 352(aa)) is amended by striking  
9 “744A(a)(4)” and inserting “744B(a)(4)”.

1 (b) Subchapter C of title VII of the Federal Food,  
2 Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is  
3 amended—

4 (1) in section 738(i)(2)(A)(ii), by striking  
5 “shall only be available” and inserting “shall be  
6 available”;

7 (2) in sections 744B(a)(2)(E)(ii)(II),  
8 744B(a)(3)(C)(ii)(III), 744B(a)(4)(D)(i)(II), and  
9 744B(a)(4)(D)(ii)(II), by inserting “for such year”  
10 after “obligation of fees” each place it appears; and

11 (3) in section 744B(i)(2)(C)—

12 (A) by inserting a comma after “Sep-  
13 tember 30, 2013”; and

14 (B) by striking the comma after “for fiscal  
15 year 2013”.

16 (c)(1) Notwithstanding section 744B(a)(2)(E)(ii) of  
17 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
18 379j-42(a)(2)(E)(ii)), the fee authorized under section  
19 744B(a)(2) of such Act for fiscal year 2013 shall be due  
20 30 calendar days after publication of the notice provided  
21 for in section 744B(a)(2)(C)(i) of such Act.

22 (2) Notwithstanding section 744B(a)(3)(C)(ii) of  
23 such Act, the fee authorized under section 744B(a)(3) of  
24 such Act for fiscal year 2013 shall be due on the later  
25 of—

1 (A) the date of submission of the abbreviated  
2 new drug application or prior approval supplement  
3 for which such fee applies; or

4 (B) 30 calendar days after publication of the  
5 notice referred to in section 744B(a)(3)(B)(i) of  
6 such Act.

7 (3) Notwithstanding section 744B(a)(4)(D)(i) of  
8 such Act, the fee authorized under section 744B(a)(4) of  
9 such Act for fiscal year 2013 shall be due not later than  
10 45 days after the publication of the notice under section  
11 744B(a)(4)(C)(i) of such Act.