

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 6433

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IN THE SENATE OF THE UNITED STATES

SEPTEMBER 20, 2012

Received

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## AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “FDA User Fee Correc-  
3 tions Act of 2012”.

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

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

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

11 (1) in section 738(i)(2)(A)(ii), by striking  
12 “shall only be available” and inserting “shall be  
13 available”;

14 (2) in sections 744B(a)(2)(E)(ii)(II),  
15 744B(a)(3)(C)(ii)(III), 744B(a)(4)(D)(i)(II), and  
16 744B(a)(4)(D)(ii)(II), by inserting “for such year”  
17 after “obligation of fees” each place it appears; and

18 (3) in section 744B(i)(2)(C)—

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

21 (B) by striking the comma after “for fiscal  
22 year 2013”.

23 (c)(1) Notwithstanding section 744B(a)(2)(E)(ii) of  
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
25 379j–42(a)(2)(E)(ii)), the fee authorized under section  
26 744B(a)(2) of such Act for fiscal year 2013 shall be due

1 30 calendar days after publication of the notice provided  
2 for in section 744B(a)(2)(C)(i) of such Act.

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

7 (A) the date of submission of the abbreviated  
8 new drug application or prior approval supplement  
9 for which such fee applies; or

10 (B) 30 calendar days after publication of the  
11 notice referred to in section 744B(a)(3)(B)(i) of  
12 such Act.

13 (3) Notwithstanding section 744B(a)(4)(D)(i) of  
14 such Act, the fee authorized under section 744B(a)(4) of  
15 such Act for fiscal year 2013 shall be due not later than  
16 45 days after the publication of the notice under section  
17 744B(a)(4)(C)(i) of such Act.

Passed the House of Representatives September 19,  
2012.

Attest:

KAREN L. HAAS,

*Clerk.*