

Public Law 112–193
112th Congress

An Act

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

Oct. 5, 2012

[H.R. 6433]

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

FDA User Fee
Corrections Act
of 2012.
21 USC 301 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the “FDA User Fee Corrections Act of 2012”.

SEC. 2. CORRECTIONS TO FDA USER FEES.

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

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

(1) in section 738(i)(2)(A)(ii), by striking “shall only be available” and inserting “shall be available”; 21 USC 379j.

(2) in sections 744B(a)(2)(E)(ii)(II), 744B(a)(3)(C)(ii)(III), 744B(a)(4)(D)(i)(II), and 744B(a)(4)(D)(ii)(II), by inserting “for such year” after “obligation of fees” each place it appears; and 21 USC 379j–42.

(3) in section 744B(i)(2)(C)—

(A) by inserting a comma after “September 30, 2013”;

and

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

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

Deadline.
21 USC 379j–42
note.

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

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

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

(3) Notwithstanding section 744B(a)(4)(D)(i) of such Act, the fee authorized under section 744B(a)(4) of such Act for fiscal year

2013 shall be due not later than 45 days after the publication of the notice under section 744B(a)(4)(C)(i) of such Act.

Approved October 5, 2012.

LEGISLATIVE HISTORY—H.R. 6433:

CONGRESSIONAL RECORD, Vol. 158 (2012):

Sept. 19, considered and passed House.

Sept. 21, considered and passed Senate.