

117TH CONGRESS
1ST SESSION

H. R. 4405

To amend the Federal Food, Drug, and Cosmetic Act to waive or reduce the amount of over-the-counter monograph fees applicable to small businesses, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 9, 2021

Mr. STEUBE introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to waive or reduce the amount of over-the-counter monograph fees applicable to small businesses, and for other purposes.

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 “Small Business FDA
5 User Fee Adjustment Act of 2021”.

1 **SEC. 2. WAIVER AND REDUCTION OF OTC MONOGRAPH**
2 **FEEES FOR SMALL BUSINESSES.**

3 (a) IN GENERAL.—Section 744M of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72) is
5 amended—

6 (1) by redesignating subsections (d) through (h)
7 as subsections (e) through (i), respectively; and

8 (2) by inserting after subsection (c) the fol-
9 lowing:

10 “(d) FEE WAIVER AND REDUCTION FOR SMALL
11 BUSINESSES.—

12 “(1) IN GENERAL.—Beginning with respect to
13 fiscal year 2022:

14 “(A) The Secretary shall waive the fee
15 under subsection (a)(2) with respect to the first
16 OTC monograph order request that a small
17 business submits to the Secretary for review.

18 “(B) The Secretary shall reduce the fees
19 that are applicable to a small business under
20 subsections (a)(1) (facility fees) and (a)(2)
21 (OTC monograph order request fees), and not
22 waived under subparagraph (A), to 25 percent
23 of the amount otherwise owed.

24 “(2) CERTIFICATION.—The Secretary shall re-
25 quire any person who applies for a waiver or reduc-
26 tion of fees under paragraph (1) to certify their

1 qualification for the waiver or reduction. The Sec-
2 retary shall periodically publish in the Federal Reg-
3 ister a list of persons making such certifications.

4 “(3) SMALL BUSINESS DEFINED.—In this sub-
5 section, the term ‘small business’ means an entity
6 that has fewer than 500 employees, including em-
7 ployees of affiliates”.

8 (b) CONFORMING CHANGE TO FEE REVENUE
9 AMOUNTS.—Section 744M(b)(2) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 379j–72(b)(2)) is
11 amended by striking “For each of the fiscal years 2022
12 through 2025” and inserting “Subject to subsection (d),
13 for each of the fiscal years 2022 through 2025”.

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