

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.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 9, 2021

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

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## 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 **FEE WAIVER AND REDUCTION FOR SMALL**  
3 **BUSINESSES.**

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

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

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

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

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

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

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

25 “(2) CERTIFICATION.—The Secretary shall re-  
26 quire any person who applies for a waiver or reduc-  
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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