

117TH CONGRESS  
2D SESSION

# H. R. 9329

To amend the Federal Food, Drug, and Cosmetic Act to allow waivers of annual establishment registration fees for small businesses, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 17, 2022

Mr. BUCSHON (for himself and Mr. YARMUTH) 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 allow waivers of annual establishment registration fees for 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 Estab-  
5 lishment Registration Waiver Act”.

6 **SEC. 2. WAIVER OF ANNUAL ESTABLISHMENT REGISTRA-**  
7 **TION FEES FOR SMALL BUSINESSES.**

8 Section 738 of the Federal Food, Drug, and Cosmetic  
9 Act (21 U.S.C. 379j) is amended—

1 (1) in subsection (a)(3)(B)—

2 (A) by striking “No fee” and inserting the  
3 following:

4 “(i) IN GENERAL.—No fee”; and

5 (B) by adding at the end the following:

6 “(ii) SMALL BUSINESSES FEE WAIV-  
7 ER.—

8 “(I) DEFINITION OF SMALL  
9 BUSINESS.—For the purposes of this  
10 clause, the term ‘small business’  
11 means an entity that reported  
12 \$1,000,000 or less of gross receipts or  
13 sales in its most recent Federal in-  
14 come tax return for a taxable year, in-  
15 cluding such returns of all of its affili-  
16 ates.

17 “(II) WAIVER.—The Secretary  
18 may grant a waiver of the fee required  
19 under subparagraph (A) for the an-  
20 nual registration (excluding the initial  
21 registration) of an establishment for a  
22 year, if the Secretary finds that the  
23 establishment is a small business and  
24 paying the fee for such year rep-  
25 represents a financial hardship to the es-

1                   tabishment as determined on the  
2                   basis of criteria established by the  
3                   Secretary.

4                   “(III) FIRMS SUBMITTING TAX  
5                   RETURNS TO THE UNITED STATES IN-  
6                   TERNAL REVENUE SERVICE.—The es-  
7                   tablishment shall support its claim  
8                   that it meets the definition under sub-  
9                   clause (I) by submission of a copy of  
10                  its most recent Federal income tax re-  
11                  turn for a taxable year, and a copy of  
12                  such returns of its affiliates, which  
13                  show an amount of gross sales or re-  
14                  ceipts that is less than the maximum  
15                  established in subclause (I). The es-  
16                  tablishment, and each of such affili-  
17                  ates, shall certify that the information  
18                  provided is a true and accurate copy  
19                  of the actual tax forms they submitted  
20                  to the Internal Revenue Service. If no  
21                  tax forms are submitted for any affil-  
22                  iate, the establishment shall certify  
23                  that the establishment has no affili-  
24                  ates.

1                   “(IV) FIRMS NOT SUBMITTING  
2                   TAX RETURNS TO THE UNITED  
3                   STATES INTERNAL REVENUE SERV-  
4                   ICE.—In the case of an establishment  
5                   that has not previously submitted a  
6                   Federal income tax return, the estab-  
7                   lishment and each of its affiliates  
8                   shall demonstrate that it meets the  
9                   definition under subclause (I) by sub-  
10                  mission of a signed certification, in  
11                  such form as the Secretary may direct  
12                  through a notice published in the Fed-  
13                  eral Register, that the establishment  
14                  or affiliate meets the criteria for a  
15                  small business and a certification, in  
16                  English, from the national taxing au-  
17                  thority, if extant, of the country in  
18                  which the establishment or, if applica-  
19                  ble, affiliate is headquartered. The  
20                  certification from such taxing author-  
21                  ity shall bear the official seal of such  
22                  taxing authority and shall provide the  
23                  establishment’s or affiliate’s gross re-  
24                  ceipts or sales for the most recent  
25                  year in both the local currency of such

1 country and in United States dollars,  
2 the exchange rate used in converting  
3 such local currency to dollars, and the  
4 dates during which these receipts or  
5 sales were collected. The establish-  
6 ment shall also submit a statement  
7 signed by the head of the establish-  
8 ment's firm or by its chief financial  
9 officer that the establishment has sub-  
10 mitted certifications for all of its af-  
11 filiates, or that the establishment has  
12 no affiliates.

13 “(V) REQUEST FOR WAIVER.—  
14 An establishment seeking a fee waiver  
15 for a year under this clause shall sub-  
16 mit supporting information to the  
17 Secretary at least 60 days before the  
18 fee is required pursuant to subpara-  
19 graph (C). The decision of the Sec-  
20 retary regarding whether an entity  
21 may receive the waiver for such year  
22 is not reviewable.”;

23 (2) in subsection (d)(2)(B)(iii), by inserting “,  
24 if extant,” after “national taxing authority”; and

1           (3) in subsection (e)(2)(B)(iii), by inserting “,  
2           if extant,” after “national taxing authority”.

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