

117TH CONGRESS
2D SESSION

S. 4385

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

IN THE SENATE OF THE UNITED STATES

JUNE 13, 2022

Mr. BRAUN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 tablishment 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”.

