

Mike Braun
Amendment #2

AMENDMENT NO. _____ Calendar No. _____

Purpose: To allow waivers of annual establishment registration fees for small businesses.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. BRAUN

Viz:

1 In section 203, strike subsection (d) and insert the
2 following:

3 (d) SMALL BUSINESSES.—Section 738 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
5 ed—

6 (1) in subsection (a)(3)(B)—

7 (A) by striking “No fee” and inserting the
8 following:

9 “(i) IN GENERAL.—No fee”; and

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

1 “(ii) SMALL BUSINESSES FEE WAIV-
2 ER.—

3 “(I) DEFINITION OF SMALL
4 BUSINESS.—For the purposes of this
5 clause, the term ‘small business’
6 means an entity that reported
7 \$1,000,000 or less of gross receipts or
8 sales in its most recent Federal in-
9 come tax return for a taxable year, in-
10 cluding such returns of all of its affili-
11 ates.

12 “(II) WAIVER.—The Secretary
13 may grant a waiver of the fee required
14 under subparagraph (A) for the an-
15 nual registration (excluding the initial
16 registration) of an establishment for a
17 year, if the Secretary finds that the
18 establishment is a small business and
19 paying the fee for such year rep-
20 resents a financial hardship to the es-
21 tablishment as determined on the
22 basis of criteria established by the
23 Secretary.

24 “(III) FIRMS SUBMITTING TAX
25 RETURNS TO THE UNITED STATES IN-

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

20 “(IV) FIRMS NOT SUBMITTING
21 TAX RETURNS TO THE UNITED
22 STATES INTERNAL REVENUE SERV-
23 ICE.—In the case of an establishment
24 that has not previously submitted a
25 Federal income tax return, the estab-

1 lishment and each of its affiliates
2 shall demonstrate that it meets the
3 definition under subclause (I) by sub-
4 mission of a signed certification, in
5 such form as the Secretary may direct
6 through a notice published in the Fed-
7 eral Register, that the establishment
8 or affiliate meets the criteria for a
9 small business and a certification, in
10 English, from the national taxing au-
11 thority, if extant, of the country in
12 which the establishment or, if applica-
13 ble, affiliate is headquartered. The
14 certification from such taxing author-
15 ity shall bear the official seal of such
16 taxing authority and shall provide the
17 establishment's or affiliate's gross re-
18 ceipts or sales for the most recent
19 year in both the local currency of such
20 country and in United States dollars,
21 the exchange rate used in converting
22 such local currency to dollars, and the
23 dates during which these receipts or
24 sales were collected. The establish-
25 ment shall also submit a statement

1 signed by the head of the establish-
2 ment's firm or by its chief financial
3 officer that the establishment has sub-
4 mitted certifications for all of its af-
5 filiates, or that the establishment has
6 no affiliates.

7 “(V) REQUEST FOR WAIVER.—

8 An establishment seeking a fee waiver
9 for a year under this clause shall sub-
10 mit supporting information to the
11 Secretary at least 60 days before the
12 fee is required pursuant to subpara-
13 graph (C). The decision of the Sec-
14 retary regarding whether an entity
15 may receive the waiver for such year
16 is not reviewable.”;

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

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