

113TH CONGRESS  
1ST SESSION

# H. R. 3631

To authorize the Commissioner of Food and Drugs to waive or reduce certain fees applicable to generic drug facilities where the fees would present a significant barrier to market entry because of limited resources available to such facilities or other circumstances.

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 2, 2013

Mr. HURT (for himself and Mr. ROE of Tennessee) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To authorize the Commissioner of Food and Drugs to waive or reduce certain fees applicable to generic drug facilities where the fees would present a significant barrier to market entry because of limited resources available to such facilities or other circumstances.

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 Manufacturer  
5 Protection Act of 2013”.

1 **SEC. 2. WAIVER OR REDUCTION OF CERTAIN FEES APPLI-**  
2 **CABLE TO GENERIC DRUG FACILITIES.**

3 (a) IN GENERAL.—Section 744B of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42) is  
5 amended—

6 (1) in subsection (b)(1)(B), by inserting “, ex-  
7 cept as provided in subsection (c)(3),” after “fees  
8 under paragraphs (2) through (4) of subsection (a)  
9 shall”; and

10 (2) in subsection (c), by adding at the end the  
11 following:

12 “(3) FEE WAIVERS.—

13 “(A) STANDARD.—The Secretary shall  
14 grant to a person that owns a generic drug fa-  
15 cility a waiver from or a reduction of one or  
16 more fees assessed to that person under sub-  
17 section (a) where the Secretary finds that the  
18 assessment of the fee would present a signifi-  
19 cant barrier to market entry because of limited  
20 resources available to such person or other cir-  
21 cumstances.

22 “(B) CONSIDERATIONS.—In determining  
23 whether to grant a waiver or reduction of a fee  
24 under subparagraph (A), the Secretary shall  
25 consider only the circumstances and assets of

1 the person involved and any affiliate of the per-  
2 son.

3 “(C) WRITTEN REQUESTS.—To qualify for  
4 consideration for a waiver or reduction under  
5 subparagraph (A), a person shall submit to the  
6 Secretary a written request for such waiver or  
7 reduction not later than 180 days after the fee  
8 is due.

9 “(D) DEFINITION.—In this paragraph, the  
10 term ‘person that owns a generic drug facility’  
11 means a person that owns a facility which is  
12 identified or intended to be identified in at least  
13 one generic drug submission that is pending or  
14 approved to produce one or more finished dos-  
15 age forms of a human generic drug.”.

16 (b) APPLICABILITY.—The amendments made by this  
17 section apply with respect to fees authorized to be assessed  
18 and collected for any of fiscal years 2014 through 2017.

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