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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.

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Small Manufacturer Protection Act of 2013''.

SEC. 2. WAIVER OR REDUCTION OF CERTAIN FEES APPLICABLE TO GENERIC DRUG FACILITIES.

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

(1) in subsection (b)(1)(B), by inserting ", except as provided in subsection (c)(3)," after "fees under paragraphs (2) through (4) of subsection (a) shall"; and

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

"(3) FEE WAIVERS.—

"(A) STANDARD.—The Secretary shall grant to a person that owns a generic drug facility a waiver from or a reduction of one or more fees assessed to that person under subsection (a) where the Secretary finds that the assessment of the fee would present a significant barrier to market entry because of limited resources available to such person or other circumstances.

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

the person involved and any affiliate of the person.

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

''(D) DEFINITION.—In this paragraph, the term 'person that owns a generic drug facility' means a person that owns a facility which is identified or intended to be identified in at least one generic drug submission that is pending or approved to produce one or more finished dosage forms of a human generic drug.''.

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

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