

116TH CONGRESS
1ST SESSION

H. R. 1362

To amend the Federal Food, Drug, and Cosmetic Act to allow, during a lapse in appropriations, acceptance of certain device submissions and registrations with the corresponding fees made available for obligation and expenditure for the process for the review of device applications, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 26, 2019

Mr. EMMER introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow, during a lapse in appropriations, acceptance of certain device submissions and registrations with the corresponding fees made available for obligation and expenditure for the process for the review of device applications, 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 “Medical Innovation
5 Never Stops Act of 2019”.

1 **SEC. 2. AUTHORITY DURING A LAPSE IN APPROPRIATIONS.**

2 Chapter VII of the Federal Food, Drug, and Cos-
3 metic Act is amended by inserting after section 738A (21
4 U.S.C. 379j–1) the following:

5 **“SEC. 738B. AUTHORITY DURING A LAPSE IN APPROPRIA-**
6 **TIONS.**

7 “(a) ACCEPTANCE OF SUBMISSIONS AND REGISTRA-
8 TIONS; APPLICATION OF FEES.—During any period in
9 which appropriations are not in effect for the Food and
10 Drug Administration, the Secretary shall—

11 “(1) accept a submission described in section
12 738(a)(2) and a registration described in section
13 738(a)(3) if an applicable fee has been submitted for
14 such submission or registration;

15 “(2) collect such fees in accordance with this
16 part, notwithstanding any limitation with respect to
17 the availability of appropriations in section 738; and

18 “(3) obligate and expend such fees as may be
19 so collected for the process for the review of device
20 applications.

21 “(b) APPLICATION OF PREVIOUSLY PAID FEES.—

22 “(1) IN GENERAL.—During any period in which
23 appropriations are not in effect for the Food and
24 Drug Administration, the Secretary may obligate
25 and expend for the process for the review of device
26 applications any fees—

1 “(A) that were paid before such period
2 began for submissions described in section
3 738(a)(2), but with respect to which a submis-
4 sion has not been received; and

5 “(B) that were paid before such period
6 began for registrations described in section
7 738(a)(3), but with respect to which a remitter
8 has not been identified.

9 “(2) SUBSEQUENTLY RECEIVED SUBMISSION OR
10 REGISTRATION.—Notwithstanding the obligation or
11 expenditure of a fee for the process for the review
12 of device applications pursuant to paragraph (1),
13 such fee shall be deemed to have been paid for pur-
14 poses of section 738(f)(1) if the Secretary subse-
15 quently receives a submission or registration for
16 such fee.

17 “(c) EFFECT OF ENACTMENT OF SUBSEQUENT AP-
18 PROPRIATIONS.—Upon the enactment of an appropriation
19 for fees under section 738 for a fiscal year, or a general
20 appropriation bill providing appropriations for the Food
21 and Drug Administration for a fiscal year without provi-
22 sion for such device fees, following a period during which
23 a collection, obligation, or expenditure of fees occurs pur-
24 suant to subsection (a) or (b) for such fiscal year—

1 “(1) such collection, obligation, and expenditure
2 shall be charged to such appropriation (if any); and
3 “(2) amounts made available pursuant to such
4 subsection shall not be available after the date of the
5 enactment of such appropriation or general appro-
6 priation bill.”.

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