.....

(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. _____

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

Mr. EMMER introduced the following bill; which was referred to the Committee on _____

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.

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 ''Medical Innovation Never Stops Act of 2019''.

SEC. 2. AUTHORITY DURING A LAPSE IN APPROPRIATIONS.

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

''SEC. 738B. AUTHORITY DURING A LAPSE IN APPROPRIATIONS.

''(a) ACCEPTANCE OF SUBMISSIONS AND REGISTRATIONS; APPLICATION OF FEES.—During any period in which appropriations are not in effect for the Food and Drug Administration, the Secretary shall—

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

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

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

''(b) APPLICATION OF PREVIOUSLY PAID FEES.—

''(1) IN GENERAL.—During any period in which appropriations are not in effect for the Food and

Drug Administration, the Secretary may obligate and expend for the process for the review of device applications any fees—

"(A) that were paid before such period began for submissions described in section 738(a)(2), but with respect to which a submission has not been received; and

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

"(2) SUBSEQUENTLY RECEIVED SUBMISSION OR REGISTRATION.—Notwithstanding the obligation or expenditure of a fee for the process for the review of device applications pursuant to paragraph (1), such fee shall be deemed to have been paid for purposes of section 738(f)(1) if the Secretary subsequently receives a submission or registration for such fee.

"(c) EFFECT OF ENACTMENT OF SUBSEQUENT APPROPRIATIONS.—Upon the enactment of an appropriation for fees under section 738 for a fiscal year, or a general appropriation bill providing appropriations for the Food and Drug Administration for a fiscal year without provision for such device fees, following a period during which

a collection, obligation, or expenditure of fees occurs pursuant to subsection (a) or (b) for such fiscal year—

''(1) such collection, obligation, and expenditure shall be charged to such appropriation (if any); and

''(2) amounts made available pursuant to such subsection shall not be available after the date of the enactment of such appropriation or general appropriation bill.''.