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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to establish special rules to provide for continued review of human drug and device submissions during a lapse of appropriations, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish special rules to provide for continued review of human drug and device submissions during a lapse of appropriations, 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 “Getting Innovations
5 to Patients During Shutdowns Act”.

1 **SEC. 2. SPECIAL RULES TO PROVIDE FOR CONTINUED RE-**
2 **VIEW OF HUMAN DRUG AND DEVICE SUBMIS-**
3 **SIONS DURING A LAPSE OF APPROPRIA-**
4 **TIONS.**

5 (a) HUMAN DRUG SUBMISSIONS.—Section 736(e) of
6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 379h(e)) is amended—

8 (1) by striking “A human drug application”
9 and inserting the following:

10 “(1) IN GENERAL.—A human drug applica-
11 tion”; and

12 (2) by adding at the end the following:

13 “(2) SPECIAL RULE FOR LAPSE OF APPROPRIA-
14 TIONS.—

15 “(A) IN GENERAL.—Notwithstanding para-
16 graph (1), during any period for which there is
17 a lapse of appropriations for the programs and
18 activities of the Food and Drug Administration,
19 or for the collection of fees used to support the
20 process for the review of drug applications, the
21 Secretary—

22 “(i) may accept for filing an applica-
23 tion or supplement described in paragraph
24 (1) if the application or supplement is
25 complete except for the payment of a fee
26 required under subsection (a); and

1 “(ii) shall extend the deadline for the
2 payment of such fee to the date that is 7
3 days after the last day of such period.

4 “(B) EFFECT OF FAILURE TO PAY FEES
5 ON OR BEFORE EXTENDED DEADLINE DATE.—
6 If the Secretary accepts an application or sup-
7 plement subject to an extended deadline for the
8 payment of a fee under subparagraph (A), and
9 the person subject to the fee does not pay the
10 fee on or before the date of the extended dead-
11 line—

12 “(i) the Secretary shall consider the
13 application or supplement to be incomplete
14 and deem the application or supplement
15 not accepted; and

16 “(ii) in no case shall the Secretary
17 clear, authorize, or approve the application
18 or supplement (or any related application
19 or supplement) until such fee is paid.”.

20 (b) DEVICE SUBMISSIONS.—Section 738(f)(1) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 379j(f)(1)) is amended—

23 (1) by striking “A premarket application” and
24 inserting the following:

1 “(A) IN GENERAL.—A premarket applica-
2 tion”; and

3 (2) by adding at the end the following:

4 “(B) SPECIAL RULE FOR LAPSE OF APPRO-
5 PRIATIONS.—

6 “(i) IN GENERAL.—Notwithstanding
7 subparagraph (A), during any period for
8 which there is a lapse of appropriations for
9 the programs and activities of the Food
10 and Drug Administration, or for the collec-
11 tion of fees used to support the process for
12 the review of device applications, the Sec-
13 retary—

14 “(I) may accept a submission de-
15 scribed in subparagraph (A) if the
16 submission is complete except for the
17 payment of a fee required under sub-
18 section (a)(2) or (a)(3) relating to the
19 submission; and

20 “(II) shall extend the deadline
21 for the payment of such fee to the
22 date that is 7 days after the last day
23 of such period.

24 “(ii) EFFECT OF FAILURE TO PAY
25 FEES ON OR BEFORE EXTENDED DEAD-

1 LINE DATE.—If the Secretary accepts a
2 submission subject to an extended deadline
3 for the payment of a fee under clause (i),
4 and the person subject to the fee does not
5 pay the fee on or before the date of the ex-
6 tended deadline—

7 “(I) the Secretary shall deem the
8 submission not accepted; and

9 “(II) in no case shall the Sec-
10 retary clear, authorize, or approve the
11 submission (or any related submis-
12 sion) until such fee is paid.”.