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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act with respect to persons who, with respect to devices, are accredited to perform certain reviews or inspections.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to persons who, with respect to devices, are accredited to perform certain reviews or inspections.

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 “FDA Renewing Effi-
5 ciency From Outside Reviewer Management Act of 2011”.

1 **SEC. 2. PERSONS ACCREDITED TO REVIEW REPORTS**
2 **UNDER 510(K) AND MAKE RECOMMENDA-**
3 **TIONS FOR INITIAL CLASSIFICATION.**

4 (a) TIME PERIOD FOR REVIEW OF RECOMMENDA-
5 TIONS OF ACCREDITED PERSONS.—Section 523(a) of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 360m(a)) is amended—

8 (1) in paragraph (1), by striking “reviewing re-
9 ports” and inserting “reviewing and making rec-
10 ommendations to the Secretary regarding reports”;
11 and

12 (2) in paragraph (2), by amending subpara-
13 graph (B) to read as follows:

14 “(B) TIME PERIOD FOR REVIEW.—Not
15 later than 30 days after the date on which the
16 Secretary is notified under subparagraph (A) by
17 an accredited person with respect to a rec-
18 ommendation regarding a report submitted
19 under section 510(k) or an initial classification
20 of a device, the Secretary shall make a deter-
21 mination with respect to the recommendation.
22 If the Secretary fails to make such a determina-
23 tion by the end of such 30-day period, the rec-
24 ommendation is deemed to be accepted by the
25 Secretary.”.

1 (b) ACCESS TO DEVICE INFORMATION.—Paragraph
2 (2) of section 523(a) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360m(a)) is amended by adding at
4 the end the following:

5 “(D) ACCESS TO DEVICE INFORMATION.—
6 Subject to section 301(j), for the purpose of
7 providing accredited persons with additional in-
8 formation to review reports submitted under
9 section 510(k) and make recommendations re-
10 garding the initial classification of devices, the
11 Secretary shall regularly publish—

12 “(i) detailed decision summaries for
13 each clearance of a device under section
14 510(k), classification of a device under sec-
15 tion 513, approval of an application for a
16 device under section 515, or grant of an
17 exemption for a device under section
18 520(m), occurring after the date of the en-
19 actment of this subparagraph; and

20 “(ii) total product life cycles informa-
21 tion for devices.”.

22 (c) TYPES OF DEVICES TO BE REVIEWED.—Para-
23 graph (3) of section 523(a) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 360m(a)) is amended to read
25 as follows:

1 “(3) CERTAIN DEVICES.—

2 “(A) IN GENERAL.—An accredited person
3 may be used to perform a review regarding any
4 report submitted under section 510(k) except
5 that an accredited person—

6 “(i) may not be used to perform a re-
7 view of a class III device; and

8 “(ii) may be used to perform a review
9 of a class II device which is intended to be
10 permanently implantable or life sustaining
11 or supporting only if a notification is sub-
12 mitted under subparagraph (B).

13 “(B) NOTIFICATION OF INTENT TO PER-
14 FORM A REVIEW.—Before performing a review
15 of a report submitted under section 510(k) for
16 a class II device which is intended to be perma-
17 nently implantable or life sustaining or sup-
18 porting, an accredited person shall submit to
19 the Secretary a notification of the person’s in-
20 tent to perform the review. If the Secretary
21 does not object within 60 days after receipt of
22 such a notification, the Secretary is deemed to
23 allow the accredited person to perform such re-
24 view. If the Secretary objects to performance of
25 the review by the accredited person, the Sec-

1 retary shall specify in writing the basis for the
2 objection, including any reasons why the ac-
3 credited person is not capable of performing the
4 review in a manner which provides a reasonable
5 assurance of the safety and effectiveness of the
6 device for its intended purpose.”.

7 (d) ACCREDITATION.—Section 523(b) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 360m(b)) is
9 amended—

10 (1) in paragraph (2)—

11 (A) in the heading of subparagraph (C), by
12 inserting “AND TRAINING” after “AUDITING”;

13 (B) in subparagraph (C)—

14 (i) in clause (i), by striking “and” at
15 the end;

16 (ii) by redesignating clause (ii) as
17 clause (iii); and

18 (iii) by inserting after clause (i) the
19 following:

20 “(ii) provide for the initial training
21 and periodic updating of training of such
22 person; and”;

23 (C) by adding at the end the following:

24 “(E) PERIODIC REACCREDITATION.—

1 “(i) PERIOD.—Subject to suspension
2 or withdrawal under subparagraph (B),
3 any accreditation under this section shall
4 be valid for a period of 3 years after its
5 issuance.

6 “(ii) RESPONSE TO REACCREDITATION
7 REQUEST.—Upon the submission of a re-
8 quest by an accredited person to be re-
9 accredited under this section, the Secretary
10 shall approve or deny such request not
11 later than 60 days after receipt of the re-
12 quest.

13 “(iii) CRITERIA.—Not later than 120
14 days after the date of the enactment of
15 this subparagraph, the Secretary shall es-
16 tablish and publish in the Federal Register
17 criteria to reaccredit or deny reaccredita-
18 tion to persons under this section. The re-
19 accreditation of persons under this section
20 shall specify the particular activities under
21 subsection (a) for which such persons are
22 accredited.”;

23 (2) in paragraph (3)—

24 (A) in subparagraph (A), by inserting “a
25 sole practitioner or” after “may not be”;

1 (B) in subparagraph (B), by striking
2 “such a manufacturer, supplier, or vendor” and
3 inserting “a manufacturer, supplier, or vendor
4 of devices of the type for which such person is
5 accredited”; and

6 (C) in subparagraph (D), by striking “de-
7 vices” and inserting “devices of the type for
8 which such person is accredited”;

9 (3) by striking paragraph (4) (relating to selec-
10 tion of accredited persons); and

11 (4) by redesignating paragraph (5) as para-
12 graph (4).

13 (e) DURATION OF AUTHORITY.—Section 523(c) of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 360m(c)) is amended by striking “October 1, 2012” and
16 inserting “October 1, 2017”.

17 (f) REPORT.—Section 523(d) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 360m(d)) is amended
19 by striking “January 10, 2007” and inserting “January
20 15, 2015”.

21 **SEC. 3. PERSONS ACCREDITED TO CONDUCT INSPECTIONS.**

22 Section 704(g)(11) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by strik-
24 ing “October 1, 2012” and inserting “October 1, 2017”.