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112TH CONGRESS
1ST SESSION

H. R. 3205

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

OCTOBER 14, 2011

Mr. PAULSEN (for himself, Mr. ALTMIRE, Mr. KINZINGER of Illinois, Mr. GUTHRIE, Mr. CASSIDY, Mr. SHIMKUS, Mrs. MCMORRIS RODGERS, Mrs. BLACKBURN, Mr. LATTA, Mr. KLINE, Mrs. BACHMANN, Mr. CRAVAACK, Mrs. BONO MACK, and Mr. BILBRAY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

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 ''FDA Renewing Efficiency From Outside Reviewer Management Act of 2011''.

SEC. 2. PERSONS ACCREDITED TO REVIEW REPORTS UNDER 510(k) AND MAKE RECOMMENDATIONS FOR INITIAL CLASSIFICATION.

(a) TIME PERIOD FOR REVIEW OF RECOMMENDATIONS OF ACCREDITED PERSONS.—Section 523(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m(a)) is amended—

(1) in paragraph (1), by striking ''reviewing reports'' and inserting ''reviewing and making recommendations to the Secretary regarding reports''; and

(2) in paragraph (2), by amending subparagraph (B) to read as follows:

''(B) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation regarding a report submitted under section 510(k) or an initial classification of a device, the Secretary shall make a determination with respect to the recommendation. If the Secretary fails to make such a determination by the end of such 30-day period, the recommendation is deemed to be accepted by the Secretary.''.

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

"(D) ACCESS TO DEVICE INFORMATION.—Subject to section 301(j), for the purpose of providing accredited persons with additional information to review reports submitted under section 510(k) and make recommendations regarding the initial classification of devices, the Secretary shall regularly publish—

"(i) detailed decision summaries for each clearance of a device under section 510(k), classification of a device under section 513, approval of an application for a device under section 515, or grant of an exemption for a device under section 520(m), occurring after the date of the enactment of this subparagraph; and

"(ii) total product life cycles information for devices.".

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

''(3) CERTAIN DEVICES.—

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

''(i) may not be used to perform a review of a class III device; and

''(ii) may be used to perform a review of a class II device which is intended to be permanently implantable or life sustaining or supporting only if a notification is submitted under subparagraph (B).

''(B) NOTIFICATION OF INTENT TO PERFORM A REVIEW.—Before performing a review of a report submitted under section 510(k) for a class II device which is intended to be permanently implantable or life sustaining or supporting, an accredited person shall submit to the Secretary a notification of the person's intent to perform the review. If the Secretary does not object within 60 days after receipt of such a notification, the Secretary is deemed to allow the accredited person to perform such review. If the Secretary objects to performance of the review by the accredited person, the Sec-

retary shall specify in writing the basis for the objection, including any reasons why the accredited person is not capable of performing the review in a manner which provides a reasonable assurance of the safety and effectiveness of the device for its intended purpose.''.

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

(1) in paragraph (2)—

(A) in the heading of subparagraph (C), by inserting ''AND TRAINING'' after ''AUDITING'';

(B) in subparagraph (C)—

(i) in clause (i), by striking ''and'' at the end;

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

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

''(ii) provide for the initial training and periodic updating of training of such person; and''; and

(C) by adding at the end the following:

''(E) PERIODIC REACCREDITATION.—

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

''(ii) RESPONSE TO REACCREDITATION REQUEST.—Upon the submission of a request by an accredited person to be reaccredited under this section, the Secretary shall approve or deny such request not later than 60 days after receipt of the request.

''(iii) CRITERIA.—Not later than 120 days after the date of the enactment of this subparagraph, the Secretary shall establish and publish in the Federal Register criteria to reaccredit or deny reaccreditation to persons under this section. The reaccreditation of persons under this section shall specify the particular activities under subsection (a) for which such persons are accredited.'';

(2) in paragraph (3)—

(A) in subparagraph (A), by inserting ''a sole practitioner or'' after ''may not be'';

(B) in subparagraph (B), by striking ''such a manufacturer, supplier, or vendor'' and inserting ''a manufacturer, supplier, or vendor of devices of the type for which such person is accredited''; and

(C) in subparagraph (D), by striking ''devices'' and inserting ''devices of the type for which such person is accredited'';

(3) by striking paragraph (4) (relating to selection of accredited persons); and

(4) by redesignating paragraph (5) as paragraph (4).

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

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

SEC. 3. PERSONS ACCREDITED TO CONDUCT INSPECTIONS.

Section 704(g)(11) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by striking ''October 1, 2012'' and inserting ''October 1, 2017''.

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