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114TH CONGRESS
1ST SESSION

H. R. 2426

To amend the Federal Food, Drug, and Cosmetic Act with respect to easing regulatory burden with respect to certain class I and class II devices.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. SHIMKUS 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 easing regulatory burden with respect to certain class I and class II devices.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. EASING REGULATORY BURDEN WITH RESPECT TO CERTAIN CLASS I AND CLASS II DEVICES.

(a) CLASS I DEVICES.—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended—

(1) by striking ''A report under subsection (k)'' and inserting ''(1) A report under subsection (k)''; and

(2) by adding at the end the following new paragraph:

''(2) Not later than 120 days after the date of the enactment of the 21st Century Cures Act, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

''(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

''(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.''.

(b) CLASS II DEVICES.—Section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) is amended—

(1) by striking paragraph (1) and inserting the following new paragraph:

''(1) The Secretary shall—

''(A) not later than 60 days after the date of the enactment of the 21st Century Cures Act—

''(i) publish in the Federal Register a notice that contains a list of each type of class II

device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

''(ii) provide for a period of not less than 60 days for public comment beginning on the date of the publication of such notice; and

''(B) not later than 180 days after the date of the enactment of 21st Century Cures Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices contained in the list published under subparagraph (A).'';

(2) in paragraph (2)—

(A) by striking ''1 day after the date of publication of a list under this subsection,'' and inserting ''1 day after the date of publication of the final list under paragraph (1)(B),''; and

(B) by striking ''30-day period'' and inserting ''60-day period''; and

(3) by adding at the end the following new paragraph:

''(3) Upon the publication of the final list under paragraph (1)(B)—

''(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

''(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.''.

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