

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

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.

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. EASING REGULATORY BURDEN WITH RESPECT**
4 **TO CERTAIN CLASS I AND CLASS II DEVICES.**

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

8 (1) by striking “A report under subsection (k)”
9 and inserting “(1) A report under subsection (k)”;
10 and

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

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

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

13 “(B) the classification regulation applicable to
14 each such type of device shall be deemed amended
15 to incorporate such exemption.”.

16 (b) CLASS II DEVICES.—Section 510(m) of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360(m))
18 is amended—

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

21 “(1) The Secretary shall—

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

24 “(i) publish in the Federal Register a no-
25 tice that contains a list of each type of class II

1 device that the Secretary determines no longer
2 requires a report under subsection (k) to pro-
3 vide reasonable assurance of safety and effec-
4 tiveness; and

5 “(ii) provide for a period of not less than
6 60 days for public comment beginning on the
7 date of the publication of such notice; and

8 “(B) not later than 180 days after the date of
9 the enactment of 21st Century Cures Act, publish in
10 the Federal Register a list representing the Sec-
11 retary’s final determination with respect to the de-
12 vices contained in the list published under subpara-
13 graph (A).”;

14 (2) in paragraph (2)—

15 (A) by striking “1 day after the date of
16 publication of a list under this subsection,” and
17 inserting “1 day after the date of publication of
18 the final list under paragraph (1)(B),”; and

19 (B) by striking “30-day period” and in-
20 serting “60-day period”; and

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

23 “(3) Upon the publication of the final list under para-
24 graph (1)(B)—

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

4 “(B) the classification regulation applicable to
5 each such type of device shall be deemed amended
6 to incorporate such exemption.”.

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