

114TH CONGRESS
1ST SESSION

H. R. 2425

To amend the Federal Food, Drug, and Cosmetic Act with respect to the
recognition of standards.

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 the recognition of standards.

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. RECOGNITION OF STANDARDS.**

4 Section 514(c) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 360d(c)) is amended—

6 (1) in paragraph (1), by inserting after sub-
7 paragraph (B) the following new subparagraphs:

8 “(C)(i) Any person may submit a request
9 for recognition under subparagraph (A) of all
10 or part of an appropriate standard established

1 by a nationally or internationally recognized
2 standard organization.

3 “(ii) Not later than 60 days after the Sec-
4 retary receives such a request, the Secretary
5 shall—

6 “(I) make a determination to recog-
7 nize all, part, or none of the standard that
8 is the subject of the request; and

9 “(II) issue to the person who sub-
10 mitted such request a response in writing
11 that states the Secretary’s rationale for
12 that determination, including the scientific,
13 technical, regulatory, or other basis for
14 such determination;

15 “(iii) The Secretary make a response
16 issued under clause (ii)(II) publicly available, in
17 such manner as the Secretary determines ap-
18 propriate.

19 “(iv) The Secretary shall take such actions
20 as may be necessary to implement all or part of
21 a standard recognized under subclause (I), in
22 accordance with subparagraph (A).

23 “(D) The Secretary shall make publicly
24 available, in such manner as the Secretary de-
25 termines appropriate, the rationale for recogni-

1 tion under subparagraph (A) of part of a stand-
2 ard, including the scientific, technical, regu-
3 latory, or other basis for such recognition.”;
4 and

5 (2) by adding at the end the following new
6 paragraphs:

7 “(4) TRAINING ON USE OF STANDARDS.—The
8 Secretary shall provide to all employees of the Food
9 and Drug Administration who review premarket sub-
10 missions for devices periodic training on the concept
11 and use of recognized standards for purposes of
12 meeting a premarket submission requirement or
13 other applicable requirement under this Act, includ-
14 ing standards relevant to an employee’s area of de-
15 vice review.

16 “(5) GUIDANCE.—

17 “(A) DRAFT GUIDANCE.—The Secretary
18 shall publish guidance identifying the principles
19 for recognizing standards under this section. In
20 publishing such guidance, the Secretary shall
21 consider the experience with, and reliance on, a
22 standard by other Federal regulatory authori-
23 ties and the device industry, and whether rec-
24 ognition of a standard will promote harmoni-

1 zation among regulatory authorities in the regu-
2 lation of devices.

3 “(B) TIMING.—The Secretary shall pub-
4 lish—

5 “(i) draft guidance under subpara-
6 graph (A) not later than 12 months after
7 the date of the enactment of the 21st Cen-
8 tury Cures Act; and

9 “(ii) final guidance not later than 12
10 months of the close of the public comment
11 period for the draft guidance under clause
12 (i).”.

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