

115TH CONGRESS
1ST SESSION

H. R. 2144

To amend the Federal Food, Drug, and Cosmetic Act to provide for the appropriate, risk-based classification of device accessories based on their intended uses.

IN THE HOUSE OF REPRESENTATIVES

APRIL 25, 2017

Mrs. MIMI WALTERS of California (for herself and Ms. KUSTER of New Hampshire) 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 to provide for the appropriate, risk-based classification of device accessories based on their intended uses.

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 (a) SHORT TITLE.—This Act may be cited as the
5 “Risk-Based Classification of Accessories Act of 2017”.

6 (b) FINDINGS.—The Congress finds that there is a
7 need for an appropriate process for the timely classifica-
8 tion of device accessories, in accordance with the 21st Cen-

1 tury Cures Act (Public Law 114–255), such that acces-
2 sories are classified in accordance with their intended uses.

3 **SEC. 2. RISK-BASED CLASSIFICATION OF ACCESSORIES.**

4 Section 513(b)(9) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 360c(b)(9)) is amended to read
6 as follows:

7 “(9)(A) Subject to the succeeding subpara-
8 graphs of this paragraph, the Secretary shall classify
9 an accessory under this section based on the in-
10 tended use of the accessory, notwithstanding the
11 classification of any other device with which such ac-
12 cessory is intended to be used.

13 “(B) In the case of an accessory that, as of De-
14 cember 13, 2016, has been classified in accordance
15 with subparagraph (A), such classification shall con-
16 tinue to apply to such accessory.

17 “(C)(i) In the case of an accessory that has
18 been cleared under section 510(k) or approved under
19 section 515 based on the classification of another de-
20 vice with which such accessory is intended to be
21 used, and the Secretary has established a classifica-
22 tion for such accessory in accordance with subpara-
23 graph (A), the manufacturer of such accessory may,
24 in lieu of submitting a request for classification of

1 such accessory, submit a written notification to the
2 Secretary identifying such classification.

3 “(ii) Unless the Secretary, not later than 30
4 days after receiving a notification under clause (i),
5 informs the manufacturer involved that the Sec-
6 retary does not agree that the classification identi-
7 fied in such notification is appropriate for the acces-
8 sory, the accessory shall be automatically reclassified
9 in the classification so identified.

10 “(D)(i) In the case of a device intended to be
11 used with an accessory that has not been classified
12 by the Secretary in accordance with subparagraph
13 (A), the person filing an application for premarket
14 approval of such device under section 515 or a re-
15 port under section 510(k) for clearance of such de-
16 vice, may, at the time such application or report (as
17 applicable) is filed, include with such application—

18 “(I) a recommendation for the proper clas-
19 sification of the accessory pursuant to such sub-
20 paragraph; and

21 “(II) such appropriate information to sup-
22 port the recommendation as may be specified by
23 the Secretary.

24 “(ii) The Secretary’s response under section
25 515(d) or section 510(n) (as applicable) to an appli-

1 cation or report described in clause (i) shall also
2 contain the Secretary's approval or denial of the pro-
3 posed classification of the accessory involved.

4 “(iii) The Secretary's evaluation of an accessory
5 under clause (i) shall constitute an order estab-
6 lishing a new classification for such accessory for the
7 specified intended use or uses of such accessory and
8 for any accessory with the same intended use or uses
9 as such accessory.

10 “(E)(i) A manufacturer of an accessory that
11 has been previously classified by the Secretary based
12 on the intended use of another device with which
13 such accessory is intended to be used, through the
14 approval of such other device under section 515(c),
15 the clearance of such device under section 510(k), or
16 the submission of a petition for classification under
17 section 513(f)(2), and that has not been classified by
18 the Secretary in accordance with subparagraph (A),
19 may make a written submission to the Secretary
20 containing a recommendation for the appropriate
21 classification of the accessory based on the intended
22 use or uses of the accessory. Such submission may
23 include appropriate information to support the rec-
24 ommendation as may be specified by the Secretary.

1 “(ii) The Secretary shall respond to a submis-
2 sion made under clause (i) not later than 60 days
3 after receiving such submission by approving or de-
4 nying the recommended classification of the acces-
5 sory. The Secretary shall provide an opportunity for
6 a manufacturer to meet with appropriate personnel
7 of the Food and Drug Administration to discuss the
8 appropriate classification of such accessory prior to
9 making a written submission.

10 “(F) Nothing in this paragraph may be con-
11 strued as precluding a manufacturer of an accessory
12 from using the classification process described in
13 section subsection (f)(2) to obtain classification of
14 such accessory.”.

15 **SEC. 3. EFFECTIVE DATE.**

16 The amendment made by section 2 shall take effect
17 on the date that is 60 days after the date of the enactment
18 of this Act.

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