I

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.

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

SECTION 1. SHORT TITLE.

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

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

tury Cures Act (Public Law 114–255), such that accessories are classified in accordance with their intended uses.

SEC. 2. RISK-BASED CLASSIFICATION OF ACCESSORIES.

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

''(9)(A) Subject to the succeeding subparagraphs of this paragraph, the Secretary shall classify an accessory under this section based on the intended use of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.

''(B) In the case of an accessory that, as of December 13, 2016, has been classified in accordance with subparagraph (A), such classification shall continue to apply to such accessory.

''(C)(i) In the case of an accessory that has been cleared under section 510(k) or approved under section 515 based on the classification of another device with which such accessory is intended to be used, and the Secretary has established a classification for such accessory in accordance with subparagraph (A), the manufacturer of such accessory may, in lieu of submitting a request for classification of

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

''(ii) Unless the Secretary, not later than 30 days after receiving a notification under clause (i), informs the manufacturer involved that the Secretary does not agree that the classification identified in such notification is appropriate for the accessory, the accessory shall be automatically reclassified in the classification so identified.

''(D)(i) In the case of a device intended to be used with an accessory that has not been classified by the Secretary in accordance with subparagraph (A), the person filing an application for premarket approval of such device under section 515 or a report under section 510(k) for clearance of such device, may, at the time such application or report (as applicable) is filed, include with such application—

''(I) a recommendation for the proper classification of the accessory pursuant to such subparagraph; and

''(II) such appropriate information to support the recommendation as may be specified by the Secretary.

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

cation or report described in clause (i) shall also contain the Secretary's approval or denial of the proposed classification of the accessory involved.

''(iii) The Secretary's evaluation of an accessory under clause (i) shall constitute an order establishing a new classification for such accessory for the specified intended use or uses of such accessory and for any accessory with the same intended use or uses as such accessory.

''(E)(i) A manufacturer of an accessory that has been previously classified by the Secretary based on the intended use of another device with which such accessory is intended to be used, through the approval of such other device under section 515(c), the clearance of such device under section 510(k), or the submission of a petition for classification under section 513(f)(2), and that has not been classified by the Secretary in accordance with subparagraph (A), may make a written submission to the Secretary containing a recommendation for the appropriate classification of the accessory based on the intended use or uses of the accessory. Such submission may include appropriate information to support the recommendation as may be specified by the Secretary.

''(ii) The Secretary shall respond to a submission made under clause (i) not later than 60 days after receiving such submission by approving or denying the recommended classification of the accessory. The Secretary shall provide an opportunity for a manufacturer to meet with appropriate personnel of the Food and Drug Administration to discuss the appropriate classification of such accessory prior to making a written submission.

''(F) Nothing in this paragraph may be construed as precluding a manufacturer of an accessory from using the classification process described in section subsection (f)(2) to obtain classification of such accessory.''.

SEC. 3. EFFECTIVE DATE.

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

○