AMENDMENT TO COMMITTEE PRINT OF H.R. 2430

OFFERED BY M__. _____

At the end of subtitle B of title VI of the committee print, insert the following section:

SEC. 614. RISK-BASED CLASSIFICATION OF ACCESSORIES.

(a) IN GENERAL.—Subsection (f) of section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following new paragraph:

''(6)(A) Subject to the succeeding subparagraphs of this paragraph, the Secretary shall, by written order, classify an accessory under this section based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.

''(B) The classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, shall continue to apply unless and until the accessory is reclassified by the Secretary, notwithstanding the classification of any other device with which such accessory is intended to be used. Nothing in

this section shall preclude the Secretary's ability to initiate the classification of an accessory through regulation or written order, as appropriate.

''(C)(i) In the case of an accessory that has been granted marketing authorization as part of a submission under section 515(c), 510(k), or paragraph (2) of this subsection with another device with which such accessory is intended to be used, and with respect to which the Secretary has issued a written order classifying such accessory type distinct from another device in accordance with subparagraph (A), the manufacturer or importer of such accessory may, in lieu of submitting a request for classification of such accessory, submit a written request to the Secretary identifying such classification. A request under this clause shall include such information to support the request as may be specified by the Secretary.

''(ii) A request under clause (i) shall include a recommendation for the proper classification of the accessory pursuant to subparagraph (A), and shall include such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a).

''(iii) The Secretary shall respond to a request under clause (i) within 90 calendar days by granting or denying the request for reclassification of the accessory.

''(iv) Within 30 calendar days after granting a request submitted under clause (i), the Secretary shall publish a notice in the Federal Register announcing such response.

''(v) A written notification that the Secretary disagrees with the classification recommended in a request pursuant to clause (ii) shall include a detailed description and justification for the determination to disagree.

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

''(I) may include a written request for the proper classification of the accessory pursuant to subparagraph (A); and

''(II) shall include in any such request such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a); and

''(III) shall, if the request under subclause (I) is requesting classification of the accessory in class II, include in the application an initial draft proposal for special controls, if special controls would be required pursuant to subsection (a)(1)(B).

''(ii) The Secretary's response under section 515(d) or section 510(n) (as applicable) to an application or report described in clause (i) shall also contain the Secretary's granting or denial of the request for 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) For accessories that have been granted marketing authorization as part of a submission for another device with which the accessory involved is intended to be used, through an application for such other device under section 515(c), a report under section 510(k), or a request for classification under paragraph (2) of this subsection, and that have not been classified by the Secretary based on the risks and appropriate level of regulatory controls in accordance with subparagraph (A):

''(i) Not later than the date that is one year after the date of enactment of the FDA Reauthorization Act of 2017 and at least once every 5 years thereafter, and as the Secretary otherwise deems appropriate, pursuant to this paragraph, the Secretary shall publish in the Federal Register a notice proposing a list of such accessories that the Secretary believes may be suitable for a distinct classification in class I and the proposed regulations for such classifications. In developing such lists, the Secretary shall consider recommendations from sponsors of device submissions and other stakeholders for accessories to be included on such lists. The notices shall provide for a period of not less than 60 calendar days for public comment. Within 180 days after the end of the comment period, the Secretary shall publish in the Federal Register a final action classifying such suitable accessories into class I.

''(ii) A manufacturer or importer of an accessory that has been granted such marketing authorization may submit to the Secretary a written request for the appropriate classification of the accessory based on the risks and appropriate level of regulatory controls as described in subparagraph (A) or (C), and shall, if the request is requesting classifica-

tion of the accessory in class II, include in the submission an initial draft proposal for special controls, if special controls would be required pursuant to subsection (a)(1)(B). Such request shall include such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a). The Secretary shall provide an opportunity for a manufacturer or importer to meet with appropriate personnel of the Food and Drug Administration to discuss the appropriate classification of such accessory prior to submitting a written request under this clause for classification of the accessory.

''(iii) The Secretary shall respond to a request made under clause (ii) not later than 90 calendar days after receiving such submission by granting or denying the request for classification of the accessory, and the Secretary shall by written order classify such accessory or deny the request. If the Secretary does not agree with the recommendation for classification submitted by the manufacturer or importer, the response shall include a detailed description and justification for such determination. Within 30 calendar days after granting such a request, the

Secretary shall publish a notice in the Federal Register announcing such response.

''(F) Nothing in this paragraph may be construed as precluding a manufacturer of an accessory of a new type from using the classification process described in section subsection (f)(2) to obtain classification of such accessory in accordance with the criteria and requirements set forth in that subsection.''.

(b) CONFORMING CHANGE.—Section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended by striking paragraph (9) (relating to classification of an accessory).

(c) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall take effect on the date that is 60 days after the date of enactment of this Act.