

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

4 “(C)(i) In the case of an accessory that has been
5 granted marketing authorization as part of a submission
6 under section 515(c), 510(k), or paragraph (2) of this sub-
7 section with another device with which such accessory is
8 intended to be used, and with respect to which the Sec-
9 retary has issued a written order classifying such acces-
10 sory type distinct from another device in accordance with
11 subparagraph (A), the manufacturer or importer of such
12 accessory may, in lieu of submitting a request for classi-
13 fication of such accessory, submit a written request to the
14 Secretary identifying such classification. A request under
15 this clause shall include such information to support the
16 request as may be specified by the Secretary.

17 “(ii) A request under clause (i) shall include a rec-
18 ommendation for the proper classification of the accessory
19 pursuant to subparagraph (A), and shall include such in-
20 formation as may be necessary for the Secretary to evalu-
21 ate, based on the least burdensome approach, the appro-
22 priate class for the accessory under subsection (a).

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

1 “(iv) Within 30 calendar days after granting a re-
2 quest submitted under clause (i), the Secretary shall pub-
3 lish a notice in the Federal Register announcing such re-
4 sponse.

5 “(v) A written notification that the Secretary dis-
6 agrees with the classification recommended in a request
7 pursuant to clause (ii) shall include a detailed description
8 and justification for the determination to disagree.

9 “(D)(i) In the case of a device intended to be used
10 with an accessory, where the accessory has been included
11 in an application for premarket approval of such device
12 under section 515 or a report under section 510(k) for
13 clearance of such device and the Secretary has not classi-
14 fied such accessory distinctly from another device in ac-
15 cordance with subparagraph (A), the person filing the ap-
16 plication or report (as applicable) at the time such applica-
17 tion or report is filed—

18 “(I) may include a written request for the prop-
19 er classification of the accessory pursuant to sub-
20 paragraph (A); and

21 “(II) shall include in any such request such in-
22 formation as may be necessary for the Secretary to
23 evaluate, based on the least burdensome approach,
24 the appropriate class for the accessory under sub-
25 section (a); and

1 “(III) shall, if the request under subclause (I)
2 is requesting classification of the accessory in class
3 II, include in the application an initial draft proposal
4 for special controls, if special controls would be re-
5 quired pursuant to subsection (a)(1)(B).

6 “(ii) The Secretary’s response under section 515(d)
7 or section 510(n) (as applicable) to an application or re-
8 port described in clause (i) shall also contain the Sec-
9 retary’s granting or denial of the request for classification
10 of the accessory involved.

11 “(iii) The Secretary’s evaluation of an accessory
12 under clause (i) shall constitute an order establishing a
13 new classification for such accessory for the specified in-
14 tended use or uses of such accessory and for any accessory
15 with the same intended use or uses as such accessory.

16 “(E) For accessories that have been granted mar-
17 keting authorization as part of a submission for another
18 device with which the accessory involved is intended to be
19 used, through an application for such other device under
20 section 515(c), a report under section 510(k), or a request
21 for classification under paragraph (2) of this subsection,
22 and that have not been classified by the Secretary based
23 on the risks and appropriate level of regulatory controls
24 in accordance with subparagraph (A):

1 “(i) Not later than the date that is one year
2 after the date of enactment of the FDA Reauthor-
3 ization Act of 2017 and at least once every 5 years
4 thereafter, and as the Secretary otherwise deems ap-
5 propriate, pursuant to this paragraph, the Secretary
6 shall publish in the Federal Register a notice pro-
7 posing a list of such accessories that the Secretary
8 believes may be suitable for a distinct classification
9 in class I and the proposed regulations for such clas-
10 sifications. In developing such lists, the Secretary
11 shall consider recommendations from sponsors of de-
12 vice submissions and other stakeholders for acces-
13 sories to be included on such lists. The notices shall
14 provide for a period of not less than 60 calendar
15 days for public comment. Within 180 days after the
16 end of the comment period, the Secretary shall pub-
17 lish in the Federal Register a final action classifying
18 such suitable accessories into class I.

19 “(ii) A manufacturer or importer of an acces-
20 sory that has been granted such marketing author-
21 ization may submit to the Secretary a written re-
22 quest for the appropriate classification of the acces-
23 sory based on the risks and appropriate level of reg-
24 ulatory controls as described in subparagraph (A) or
25 (C), and shall, if the request is requesting classifica-

1 tion of the accessory in class II, include in the sub-
2 mission an initial draft proposal for special controls,
3 if special controls would be required pursuant to
4 subsection (a)(1)(B). Such request shall include such
5 information as may be necessary for the Secretary to
6 evaluate, based on the least burdensome approach,
7 the appropriate class for the accessory under sub-
8 section (a). The Secretary shall provide an oppor-
9 tunity for a manufacturer or importer to meet with
10 appropriate personnel of the Food and Drug Admin-
11 istration to discuss the appropriate classification of
12 such accessory prior to submitting a written request
13 under this clause for classification of the accessory.

14 “(iii) The Secretary shall respond to a request
15 made under clause (ii) not later than 90 calendar
16 days after receiving such submission by granting or
17 denying the request for classification of the acces-
18 sory, and the Secretary shall by written order clas-
19 sify such accessory or deny the request. If the Sec-
20 retary does not agree with the recommendation for
21 classification submitted by the manufacturer or im-
22 porter, the response shall include a detailed descrip-
23 tion and justification for such determination. Within
24 30 calendar days after granting such a request, the

1 Secretary shall publish a notice in the Federal Reg-
2 ister announcing such response.

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

9 (b) CONFORMING CHANGE.—Section 513(b) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 360c(b)) is amended by striking paragraph (9) (relating
12 to classification of an accessory).

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

