

114TH CONGRESS
2D SESSION

S. 9

To provide for the regulation of over-the-counter hearing aids.

IN THE SENATE OF THE UNITED STATES

DECEMBER 1, 2016

Ms. WARREN (for herself and Mr. GRASSLEY) introduced the following bill;
which was read twice and referred to the Committee on Health, Edu-
cation, Labor, and Pensions

A BILL

To provide for the regulation of over-the-counter hearing
aids.

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 This Act may be cited as the “Over-the-Counter
5 Hearing Aid Act of 2016”.

6 **SEC. 2. REGULATION OF OVER-THE-COUNTER HEARING**
7 **AIDS.**

8 (a) IN GENERAL.—Section 520 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by
10 adding at the end the following:

1 “(o) REGULATION OF OVER-THE-COUNTER HEARING
2 AIDS.—

3 “(1) DEFINITION.—In this subsection, the term
4 ‘over-the-counter hearing aid’ means a device—

5 “(A) that uses the same fundamental sci-
6 entific technology as air conduction hearing
7 aids (as defined in section 874.3300 of title 21,
8 Code of Federal Regulations) (or any successor
9 regulation) or wireless air conduction hearing
10 aids (as defined in section 874.3305 of title 21,
11 Code of Federal Regulations) (or any successor
12 regulation);

13 “(B) that is intended to be used by adults
14 to compensate for perceived mild to moderate
15 hearing impairment;

16 “(C) that includes tools to allow the user
17 to control the over-the-counter hearing aid and
18 customize it to the user’s hearing needs;

19 “(D) that may—

20 “(i) use wireless technology; or

21 “(ii) include tests for self-assessment
22 of hearing loss; and

23 “(E) that is available over-the-counter,
24 without the supervision, prescription, or other
25 order, involvement, or intervention of a licensed

1 person, to consumers through in-person trans-
 2 actions, by mail, or online.

3 “(2) REGULATION.—An over-the-counter hear-
 4 ing aid shall be subject to the regulations promul-
 5 gated in accordance with section 2(b) of the Over-
 6 the-Counter Hearing Aid Act of 2016 and shall be
 7 exempt from sections 801.420 and 801.421 of title
 8 21, Code of Federal Regulations (or any successor
 9 regulations).”.

10 (b) REGULATIONS TO ESTABLISH CATEGORY.—

11 (1) IN GENERAL.—The Secretary of Health and
 12 Human Services (referred to in this section as the
 13 “Secretary”), not later than 3 years after the date
 14 of enactment of this Act, shall promulgate proposed
 15 regulations to establish a category of over-the-
 16 counter hearing aids, as defined in subsection (o) of
 17 section 520 of the Federal Food, Drug, and Cos-
 18 metic Act (21 U.S.C. 360j) as amended by sub-
 19 section (a), and, not later than 180 days after the
 20 date on which the proposed regulations are issued,
 21 shall issue such final regulations.

22 (2) REQUIREMENTS.—In promulgating the reg-
 23 ulations under paragraph (1), the Secretary shall—

24 (A) include requirements that provide rea-
 25 sonable assurances of the safety and efficacy of

1 over-the-counter hearing aids, such as appro-
2 priate consumer labeling; and

3 (B) describe the requirements under which
4 the sale of over-the-counter hearing aids is per-
5 mitted, without the supervision, prescription, or
6 other order, involvement, or intervention of a li-
7 censed person, to consumers through in-person
8 transactions, by mail, or online.

9 (3) PREMARKET NOTIFICATION.—The Sec-
10 retary shall make findings under section 510(m) of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 360(m)) to determine whether over-the-
13 counter hearing aids (as defined in section 520(o) of
14 the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 360j(o)), as amended by subsection (a)) re-
16 quire a report under section 510(k) to provide rea-
17 sonable assurance of safety and effectiveness.

18 (4) EFFECT ON STATE LAW.—No State or local
19 government shall establish or continue in effect any
20 law, regulation, order, or other requirement related
21 to the manufacturing, marketing, sale, customer
22 support, or distribution of over-the-counter hearing
23 aids (as defined in section 520(o) of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 360j(o)),
25 as amended by subsection (a)) through in-person

1 transactions, by mail, or online, that is different
2 from, in addition to, or otherwise not identical to,
3 the regulations promulgated under this subsection.

4 (c) GUIDANCE.—

5 (1) WITHDRAWAL OF GUIDANCE.—

6 (A) WITHDRAWAL.—Effective as of the
7 date of enactment of this Act, the Secretary
8 shall not use the draft guidance of the Depart-
9 ment of Health and Human Services entitled,
10 “Regulatory Requirements for Hearing Aid De-
11 vices and Personal Sound Amplification Prod-
12 ucts”, issued on November 7, 2013, as the
13 basis for any premarket review under the Fed-
14 eral Food, Drug, and Cosmetic Act (21 U.S.C.
15 301 et seq.) or for any related compliance or
16 enforcement decisions or actions.

17 (B) INTERIM GUIDANCE.—Until such time
18 as new final guidance is issued under paragraph
19 (2) to replace the guidance described in sub-
20 paragraph (A), the draft guidance entitled
21 “Guidance for Industry and FDA Staff: Regu-
22 latory Requirements for Hearing Aid Devices
23 and Personal Sound Amplification Products,”
24 issued on February 25, 2009, shall be in effect.

1 (2) NEW GUIDANCE ISSUED.—Not later than
2 the date on which final regulations are issued under
3 subsection (b), the Secretary shall update the draft
4 guidance described in paragraph (1)(A). Such up-
5 dated guidance shall clarify which products, on the
6 basis of claims or other marketing, advertising, or
7 labeling material, meet the definition of a device, as
8 defined in section 201 of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 321) and which prod-
10 ucts meet the definition of a personal sound amplifi-
11 cation product, as set forth in such guidance.

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