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, Education, Labor, and Pensions

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A BILL

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

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Over-the-Counter Hearing Aid Act of 2016''.

SEC. 2. REGULATION OF OVER-THE-COUNTER HEARING AIDS.

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

''(o) REGULATION OF OVER-THE-COUNTER HEARING AIDS.—

''(1) DEFINITION.—In this subsection, the term 'over-the-counter hearing aid' means a device—

''(A) that uses the same fundamental scientific technology as air conduction hearing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations) (or any successor regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);

''(B) that is intended to be used by adults to compensate for perceived mild to moderate hearing impairment;

''(C) that includes tools to allow the user to control the over-the-counter hearing aid and customize it to the user's hearing needs;

''(D) that may—

''(i) use wireless technology; or

''(ii) include tests for self-assessment of hearing loss; and

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

person, to consumers through in-person transactions, by mail, or online.

''(2) REGULATION.—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 2(b) of the Over-the-Counter Hearing Aid Act of 2016 and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).''.

(b) REGULATIONS TO ESTABLISH CATEGORY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), not later than 3 years after the date of enactment of this Act, shall promulgate proposed regulations to establish a category of over-the-counter hearing aids, as defined in subsection (o) of section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) as amended by subsection (a), and, not later than 180 days after the date on which the proposed regulations are issued, shall issue such final regulations.

(2) REQUIREMENTS.—In promulgating the regulations under paragraph (1), the Secretary shall—

(A) include requirements that provide reasonable assurances of the safety and efficacy of

over-the-counter hearing aids, such as appropriate consumer labeling; and

(B) describe the requirements under which the sale of over-the-counter hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

(3) PREMARKET NOTIFICATION.—The Secretary shall make findings under section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) to determine whether over-the-counter hearing aids (as defined in section 520(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(o)), as amended by subsection (a)) require a report under section 510(k) to provide reasonable assurance of safety and effectiveness.

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

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

(c) GUIDANCE.—

(1) WITHDRAWAL OF GUIDANCE.—

(A) WITHDRAWAL.—Effective as of the date of enactment of this Act, the Secretary shall not use the draft guidance of the Department of Health and Human Services entitled, ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products'', issued on November 7, 2013, as the basis for any premarket review under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or for any related compliance or enforcement decisions or actions.

(B) INTERIM GUIDANCE.—Until such time as new final guidance is issued under paragraph (2) to replace the guidance described in subparagraph (A), the draft guidance entitled ''Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,'' issued on February 25, 2009, shall be in effect.

(2) NEW GUIDANCE ISSUED.—Not later than the date on which final regulations are issued under subsection (b), the Secretary shall update the draft guidance described in paragraph (1)(A). Such updated guidance shall clarify which products, on the basis of claims or other marketing, advertising, or labeling material, meet the definition of a device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) and which products meet the definition of a personal sound amplification product, as set forth in such guidance.

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