SEC. 709. 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), as amended by section 708, is further amended by adding at the end the following:

"(q) REGULATION OF OVER-THE-COUNTER HEARING AIDS.—

"(1) DEFINITION.—

"(A) IN GENERAL.—In this subsection, the term 'over-the-counter hearing aid' means a device that—

"(i) 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);

"(ii) is intended to be used by adults age 18 and older to compensate for perceived mild to moderate hearing impairment;

"(iii) through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customize it to the user's hearing needs;

"(iv) may—

"(I) use wireless technology; or

"(II) include tests for self-assessment of hearing loss; and

"(v) 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.

"(B) EXCEPTION.—Such term does not include a personal sound amplification product intended to amplify sound for nonhearing impaired consumers in situations including hunting and bird-watching.

"(2) REGULATION.—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 709(b) of the FDA Reauthorization Act of 2017 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 (q) 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 public comment period on the proposed regulations closes, 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 effectiveness of over-the-counter hearing aids;

(B) include requirements that establish or adopt output limits appropriate for over-the-counter hearing aids;

(C) include requirements for appropriate labeling of over-the-counter hearing aids, including requirements that such labeling include a conspicuous statement that the device is only intended for adults age 18 and older, information on how consumers may report adverse events, information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss, and advisements to consult promptly with a licensed health care practitioner; and

(D) 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(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), 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 specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids (as defined in section 520(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), 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, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids.

(5) NO EFFECT ON PRIVATE REMEDIES.—Nothing in this section shall be construed to modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.

(c) NEW GUIDANCE ISSUED.—Not later than the date on which final regulations are issued under subsection (b), the Secretary shall update and finalize 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. Such updated and finalized guidance shall clarify which products, on the basis of claims or other marketing, advertising, or labeling material, meet the definition of a device 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.

(d) REPORT.—Not later than 2 years after the date on which the final regulations described in subsection (b)(1) are issued, the Secretary of Health and Human Services shall submit to Congress a report analyzing any adverse events relating to over-the-counter hearing aids (as defined in subsection (q)(1) of section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j)).