U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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September 8, 2022

The Honorable Patty Murray
Chairwoman
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Food and Drug Administration (FDA) entitled "Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids" (RIN: 0910-AI21). We received the rule on August 26, 2022. It was published in the *Federal Register* as a final rule on August 17, 2022. 87 Fed. Reg. 50698. The stated effective date is October 17, 2022.

FDA states that this final rule establishes a regulatory category for over-the-counter (OTC) hearing aids and updates the regulatory framework for hearing aids. Specifically, FDA states that the final rule defines OTC hearing aids and establishes applicable requirements, amends existing rules for consistency with the new OTC category, repeals the sale conditions applicable to hearing aids, amends the existing labeling requirements for hearing aids, and updates regulations relating to decisions on applications for exemption from federal preemption.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). The *Congressional Record* does not yet reflect Congress's receipt of the rule. However, FDA provided documentation to GAO showing the Senate and House of Representatives received the rule on August 22, 2022. Email from Regulatory Policy Analyst, FDA, to Senior Attorney, GAO, *Subject: RE: Congressional Review of Regulations Report - FDA- 0910-AI21 OTC Hearing Aids (2022-111)* (Aug. 30, 2022). Therefore, the final rule does not have the required 60-day delay in its stated effective date of October 17, 2022.

Enclosed is our assessment of FDA's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shari Brewster, Assistant General Counsel, at (202) 512-6398.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Kenneth Cohen
Director, Regulations Policy and Management Staff
Department of Health and Human Services

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"MEDICAL DEVICES; EAR, NOSE, AND THROAT DEVICES;
ESTABLISHING OVER-THE-COUNTER HEARING AIDS"
(RIN: 0910-AI21)

(i) Cost-benefit analysis

The Department of Health and Human Services, Food and Drug Administration (FDA) conducted an economic analysis of this final rule, including completion of a Regulatory Impact Analysis document. FDA estimated that, over a ten-year annualized period, the rule will result in benefits between $6 million and $147 million (with a mean estimate of $63 million) to consumers with perceived mild to moderate hearing impairment who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance, but who are currently unable to buy such products. FDA also estimated that, over the same ten-year period, the rule will result in annualized costs to hearing aid manufacturers of between $1 million and $2 million (with a mean estimate of $1 million), due to the need to change labeling of existing hearing aids and revise internal standard operating procedures in response to the rule.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603–605, 607, and 609

FDA certified that the rule will not have a significant economic impact on a substantial number of small entities. According to FDA, the estimated annualized cost of the rule over ten years is $0.009 million per firm, which FDA stated is unlikely to represent more than three to five percent of the revenue of an affected manufacturer.

(iii) Agency actions relevant to sections 202–205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532–1535

FDA determined that, for at least one year, the rule will result in expenditures that meet or exceed the Act's current inflation-adjusted threshold. FDA estimated that these expenditures will stem from the need for manufacturers to relabel current hearing aids, the need for affected parties to read and understand the rule, and the need for manufacturers to revise guidelines and standard operating procedures.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

On October 21, 2021, FDA published a proposed rule. 86 Fed. Reg. 58150. FDA stated that it received over 1,000 comments from consumers, professionals, professional associations, hearing aid manufacturers, public health organizations, public advocacy groups, Members of

Congress, and state agencies. FDA summarized and responded to these comments by category in the final rule.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501–3520

FDA determined that the rule contains information collection requirements (ICRs) under the Act. FDA stated that it submitted the ICRs to the Office of Management and Budget (OMB) for review. In particular, FDA identified the ICR titled *Medical Device Labeling Regulations* (OMB Control Number 0910-0485—Revision). For that ICR, FDA estimated a one-time capital cost burden of $10.1 million, as well as an annual recordkeeping burden of 840 hours and an annual third-party disclosure burden of 15,960 hours.

Statutory authorization for the rule

FDA promulgated the rule pursuant to sections 321, 331, 332, 333, 334, 351, 352, 355, 360, 360c, 360d, 360e, 360i, 360j, 360k, 360l, 361, 362, 371, and 374 of title 21, United States Code, as well as section 709 of Public Law 115-62, 131 Stat. 1065-67.

Executive Order No. 12866 (Regulatory Planning and Review)

FDA determined that the rule is economically significant under the Order and submitted it to OMB for review.

Executive Order No. 13132 (Federalism)

FDA determined that the rule implicates preemption provisions applicable to hearing aids in the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 310 *et seq.,* and the FDA Reauthorization Act of 2017, Pub. L. 115-52, 131 Stat. 1005 (Aug. 18, 2017). Because of the rule, FDA stated that it is unable to continue in effect certain previously-granted exemptions from preemption for state or local requirements. FDA responded to comments about preemption in the rule. FDA further stated that it will address preemption issues in the context of particular state and local requirements that the rule may preempt.