America's Hearing Healthcare Team

Dedicated to providing care for all with hearing and balance disorders.

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AMERICAN ACADEMY OF OTOLARYNGOLOGY—HEAD AND NECK SURGERY

INTERNATIONAL HEARING SOCIETY

July 21, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: America's Hearing Healthcare Team Urges Withdrawal of the Hearing Aid Rule as part of FDA's Effort to Withdraw Obsolete Rulemaking Projects (Docket No. 02N-0434 - Withdrawal of Certain Proposed Rules and Other Proposed Actions)

America's Hearing Healthcare Team (AHHT) is responding to the Food and Drug Administration's (FDA's) Notice of Intent with respect to withdrawal of certain proposed rules and other proposed actions (Docket No. 02N-0434), which was published in the April 22, 2003 Federal Register. AHHT strongly urges the inclusion of the long-pending November 1993 Advance Notice of Proposed Rulemaking with respect to hearing aids in the list of rulemaking projects that will officially be withdrawn.

AHHT is a joint initiative founded by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) and the International Hearing Society (IHS). Our mission is to ensure the best possible care for those with hearing disorders through a multi-disciplinary team approach. AHHT's efforts are endorsed by the American College of Surgeons, American Neurotology Society, American Otological Society, Cochlear Implant Association, and the Deafness Research Foundation

AHHT supports the agency's stated intent to withdraw various obsolete rulemaking projects which "dilute its ability to concentrate on higher priority regulations that are mandated by statute or necessary to address current public health issues." (68 Fed. Reg. 19766 (April 22, 2003)). One of those projects, which appears to have been omitted from the list inadvertently, was a revised hearing aid dispensing rule (Docket No. 93N-0372). We respectfully request that this proposal be added to the list of withdrawn rulemaking projects for the following reasons:

1) The Office of the Secretary of HHS has indicated that it does not support revisions to the hearing aid rule.

2) Revisions to the existing hearing aid rule are no longer listed in the Department's or FDA's listing in the Unified Agenda for rules currently under consideration.

3) The advanced notice of proposed rulemaking (ANPRM) to modify the current hearing aid rule (21 C.F.R. §801.420 and 421) was almost universally opposed by members of the hearing health team and Members of Congress for the following reasons:

   a) FDA's Center for Devices and Radiological Health (CDRH) was considering expanding its regulations dramatically to mandate specific hearing testing protocols, tester qualifications, and otherwise usurping traditional state regulatory functions.

   b) With the assistance of AAO-HNS and IHS, physicians and hearing instrument specialists voluntarily adopted an otologic "red flag" screening system to detect circumstances that could indicate treatable medical conditions requiring referral to a physician, preferably one specializing in diseases of the ear. This system seems to be working well to insure that patients are properly referred regardless of their entry point into the hearing health network.

   c) The draft proposal under consideration by FDA would have reduced access to an already underutilized device (only one in five patients who could benefit from hearing amplification actually utilize a hearing device) by directly or indirectly requiring patients to undergo expensive and unnecessary diagnostic audiological testing.

   d) The FDA proposals would likely have inconvenienced the patient and increased the cost of hearing healthcare for no discernible gain, thereby deterring utilization by requiring multiple appointments for screening, testing and fitting, or by favoring one segment of the hearing health team over another.

4) The hearing aid ANPRM fits all the criteria for inclusion on the FDA withdrawal list: (a) it is older than five years; (b) no action has been taken recently to advance the proposal; (c) the comments received are outdated and the regulatory climate has changed since the notice was released; (d) it does not address a current public health concern or priority; and (e) advancing the proposal would dilute scarce agency resources.

5) AAO-HNS and IHS and their allies among hearing health providers and consumers have been forced to expend millions of dollars, and thousands of hours of member and staff time, over the last ten years educating the agency, the Administration and the Congress concerning the issues raised by these proposals, and responding to various agency requests for information. Official withdrawal would help insure that additional resources of the professional community and the agency are not likewise squandered in the continued pursuit of a proposed "cure that would be worse than any disease."

For the reasons stated above, America's Hearing Healthcare Team encourages the agency to use this appropriate opportunity to add the hearing aid rule ANPRM (Docket No. 93N-0372) to the list set forth in "Withdrawal of Certain Proposed Rules and Other Proposed Actions."

Please contact Beverly Nissenbaum at 703/519-1537 or Karen Sealander at 202/756-8024 with any questions, clarifications, or if America's Hearing Healthcare Team may be of assistance in any way. On behalf of hearing healthcare providers and the patients they serve, thank you for your consideration.

Sincerely,

David R. Nielsen, MD
Executive Vice President
AAO-HNS

Robin Clowers, BC-HIS
Executive Director
IHS