Citizen Petition

Date: May 3, 2021

The undersigned submits this petition under Level 1 Certification for Medical Devices under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs) to request the Commissioner of Food and Drugs to amend requirements for hearing aid devices and personal sound amplification products

A. **Action Requested**

Issue:
The FDA should standardize the naming of hearing aid features and develop a rating system using international ANSI standards for the various hearing aid features.

Discussion:
Hearing aids offer several features, but it is difficult for consumers, audiologists, and hearing aid dispensers to compare brands. Manufacturers do not use common names for features, and many manufacturers trademark the terms they use. Comparing features is virtually impossible without consistent representations.

Users and parents of children with hearing loss are dependent on the audiologist or hearing aid dispenser to provide this information, which may be difficult to obtain because the audiologist/hearing aid dispenser:

1-Does not represent all manufacturers nor have familiarity with all hearing aids.

Audiologists/hearing aid dispensers are presumed to know all the aids on the market, but the reality is that they only dispense a few brands. Audiologists base the hearing aid mix on concerns that include percentage of earnings, incentive pricing, delivery schedule,

quality, and customer support. Some concerns, such as the percentage of profits, are not in the consumer's best interest.

2-May receive bonuses/equipment based on the volume of hearing aids sold.

Many hearing aid companies provide free equipment, incentives, or perks to audiologists/hearing aid dispensers based on their sales volume. This marketing program is now frowned on in the pharmaceutical business, and the FDA should eliminate the practice in the hearing aid business.

3-Has a financial incentive to maximize the likelihood of making a sale.

Audiologists/hearing aid dispensers make a substantial profit when they sell hearing aids. Critical information that may obstruct or delay the sale, such as the pros and cons of various features, may not be disclosed.

The hearing aid manufacturers also heavily fund many hearing loss organizations, which can interfere with their advocacy on this issue. Regulation of hearing aid features is critical to enable consumers to be educated and not dependent exclusively on the audiologist/ hearing aid dispenser. The information that consumers need in order to educate themselves is currently unavailable, and there is no incentive for hearing aid manufacturers or vendors to provide it. Therefore, the FDA should ensure that the data is made available to enable consumers to become better informed and more satisfied with their purchase.

Conclusion:
The FDA can bring greater transparency and accountability to the dispensing of hearing aids by standardizing the naming of hearing aid features and developing a rating system using international ANSI standards for the various hearing aid features.

Bio:

I am Janice S. Lintz, CEO of Hearing Access & Innovations (HAI) (f/k/a Hearing Access Program). I am a recipient of the 2018 Bill & Melinda Gates Foundation Goalkeepers Partnership with ThePointsGuy.com; 2016 Aspen Institute Spotlight on Health Scholar; 2016 Nominated United State of Women Changemaker by the White House, the US Department of State, the US Department of Labor, and the Aspen Institute; 2015 Delta Salutes; 2008 People magazine's Heroes Among Us; and member of the following: 2013-2015, US Access Board's Committee on Rail Vehicle Accessibility; 2009, NYC Mayor's Office Taxi of Tomorrow Stakeholder Committee; 2008-2014, New York State Interagency Council for Services to the Deaf, Deaf-Blind, and Hard of Hearing, established by Governor David A. Paterson (not currently funded); 2007-2008, US Access Board's Passenger Vessel Emergency Alarms Advisory Committee; 2006-2015, Lower East Side Tenement Museum's Advisory Board; 2004-2008 (two terms), FCC Chairman Kevin J. Martin's Consumer Advisory Committee; and a current member of the Syracuse University Burton Blatt Institute's Advisory Board since 2012. Also, I frequently write on topics related to hearing loss.

B. **Statement of Grounds**

Please see my previous FDA testimony.

Hearing aid manufacturers have no incentive to provide transparency about hearing aid features.

C. **Environmental Impact**

N/A

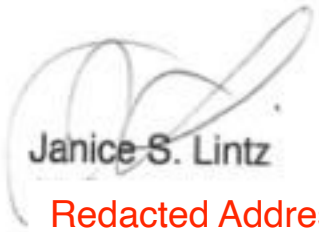
D. **Economic Impact**

To Be Supplied

E. **Certification**

"The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on

which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition."



Janice S. Lintz

Redacted Address and Phone #

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

May 11, 2021

Janice S. Lintz
Redacted Address

Sent via email to: Redacted Email

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to standardize the naming of hearing aid features and develop a rating system using international ANSI standards for the various hearing aid features was received and processed under CFR 10.30 by this office on 05/03/2021.

It was assigned docket number FDA-2021-P-0445. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-Bigby
Digitally signed by Dynna Gorham-Bigby
Date: 2021.05.11 12:55:25 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)