



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 21, 2013

Annemarie Delmugnaio
Executive Officer
Speech-Language Pathology, Audiology
and Hearing Aid Dispensers Board
State of California
Department of Consumer Affairs
2005 Evergreen Street, Suite 2100
Sacramento, CA 95815

Dear Ms. Delmugnaio:

Your application to the Food and Drug Administration for Exemption from Federal Preemption of State and Local Medical Device Requirements pertaining to hearing aids, was received by this office on 06/04/2012. It was assigned docket number FDA-2013-P-0615, and it was filed on 06/04/2012. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the application for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the application.

Sincerely,

A handwritten signature in black ink, reading "Gloria Ortega", is positioned above the typed name.

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)