STATE OF CALIFORNIA
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DEPARTMENT OF CONSUMER AFFAIRS

STATE AND CONSUMER SERVICES AGENCY • GOVERNOR EDMUND G. BROWN JR.
SPEECH-LANGUAGE PATHOLOGY & AUDIOLOGY & HEARING AID DISPENSERS BOARD
2005 EVERGREEN STREET, SUITE 2100, SACRAMENTO, CA 95815
PHONE (916) 263-2666 FAX (916) 263-2668 WWW.SPEECHANDHEARING.CA.GOV

May 30, 2012

CDRH
DR

Commissioner of Food and Drugs
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Application for Exemption from Pre-Emption of Device Requirements

Dear Commissioner:

I am Executive Officer of the California Speech Language Pathology Audiology and Hearing Aid Dispensers Board ("Board"). The Board is responsible for, among other things, the regulation and discipline of Hearing Aid Dispensers in California. The practice of Hearing Aid Dispensing in California is governed by sections 2530 et seq. of the California Business and Professions Code ("BPC").

The Board seeks information on obtaining an exemption from federal law regarding the sale of hearing aids. We submit the following in compliance with the procedures for requesting an exemption, as set forth in 21 CFR 808.20(c). Numbers in parentheses refer to the numbered requirements of that subdivision:

(1) <u>BPC 2538.23 and its History</u>

BPC 2538.23 states:

> "(a) Hearing aids may be sold by catalog or direct mail provided that:
> (1) The seller is licensed as a hearing aid dispenser in this state.
> (2) There is no fitting, selection, or adaptation of the instrument and no advice is given with respect to fitting, selection, or adaptation of the instrument and no advice is given with respect to the taking of an ear impression for an earmold by the seller.
> (3) The seller has received a statement which is signed by a physician and surgeon, audiologist, or a hearing aid dispenser, licensed by the State of California which verifies that Section 2538.36[1] and subdivision (b) of Section 2538.49[2] have been complied with.

[1] BPC section 2538.36 reads:
"(a) Whenever any of the following conditions are found to exist either from observations by the licensee or on the basis of information furnished by the prospective hearing aid user, a licensee

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(b) A copy of the statement referred to in paragraph (3) of subdivision (a) shall be retained by the seller for the period provided for in Section 2538.38[3].

(c) A licensed hearing aid dispenser who sells a hearing aid under this section shall not be required to comply with subdivision (b) of Section 2538.49."

Recent legislation, Senate Bill ("SB") 933 (2011), repealed the text of this statute from its former location at BPC section 3351.5 and moved and renumbered it to reflect the merger of the Hearing Aid

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shall, prior to fitting or selling a hearing aid to any individual, suggest to that individual in writing that his or her best interests would be served if he or she would consult a licensed physician specializing in diseases of the ear or if no such licensed physician is available in the community then to a duly licensed physician:

(1) Visible congenital or traumatic deformity of the ear.

(2) History of, or active drainage from the ear within the previous 90 days.

(3) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(4) Acute or chronic dizziness.

(5) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(6) Significant air-bone gap (when generally acceptable standards have been established).

(7) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

(8) Pain or discomfort in the ear.

(b) No referral for medical opinion need be made by any licensee in the instance of replacement only of a hearing aid that has been lost or damaged beyond repair within one year of the date of purchase. A copy of the written recommendation shall be retained by the licensee for the period provided for in Section 2538.38. A person receiving the written recommendation who elects to purchase a hearing aid shall sign a receipt for the same, and the receipt shall be kept with the other papers retained by the licensee for the period provided for in Section 2538.38. Nothing in this section required to be performed by a licensee shall mean that the licensee is engaged in the diagnosis of illness or the practice of medicine or any other activity prohibited by the provisions of this code."

[2] BPC 2538.49 reads:
"It is unlawful for a licensed hearing aid dispenser to fit or sell a hearing aid unless he or she first does all of the following:

(a) Complies with all provisions of state laws and regulations relating to the fitting or selling of hearing aids.

(b) Conducts a direct observation of the purchaser's ear canals.

(c) Informs the purchaser of the address and office hours at which the licensee shall be available for fitting or postfitting adjustments and servicing of the hearing aid or aids sold."

[3] The period of time provided for in BPC 2538.38 is seven years.

Dispenser's Bureau with the Speech-Language Pathology and Audiology Board. The statute's text, however, remains unchanged since its adoption in 1990 through SB 1916.
SB 1916 repealed a prior version of BPC section 3351.5 relating to similar subject matter (added by Stats. 1970).

This statute and is predecessor (BPC section 3351.5) have not been subject to judicial or administrative interpretation. The following is included as legislative history.[4] We apologize for the poor readability of some of the documents, but this is the nature and quality of the documents as kept on microfiche at California State Archives:

Appendix A: Governor's Chaptered Bill File, AB 532
Appendix B: Senate Third Reading of SB 1916
Appendix C: Senate Appropriations Committee file, SB 1916
Appendix D: Assembly Republican Caucus file, SB 1916
Appendix E: Governor's Chaptered Bill file, SB 1916

(2) Comparison with Federal Law

BPC section 2538.23 differs from federal regulation in the following ways:

a. ***Catalog and mail order sales of hearing aids must be made by a California-licensed hearing aid dispenser*** (BPC 2538.23(a)(1). The FDA's definition of 'dispenser' does not include a licensure requirement (21CFR801.420). However, FDA's rule (21CFR 808.1 (d)(3)) provides for the state's sovereign right to license any professions or occupations that administer, dispense, or sell devices. It is our understanding that, because of this federal rule, California is not federally pre-empted from requiring state licensure of catalog and mail order sellers. If, for some reason, this provision is indeed pre-empted, please consider this as a request for an exemption for the same

a. ***Prohibition against rendering professional services.*** In California, catalog and mail sellers must not render professional hearing aid dispenser services (BPC 2538.23(a)(2)). No federal prohibition exists against the rendering of professional hearing aid dispenser services in connection with catalog or mail sales.

b. ***Observation of ear canals.*** Federal regulation requires a medical evaluation before the purchase of a hearing aid (21 CFR 801.421(a)(1)). Such a medical evaluation may be waived (21 CFR 801.421(a)(2)). In California, the direct observation of a purchaser's ear canals, performed by either a physician and surgeon, audiologist, or hearing aid dispenser, may not be waived (BPC 2538.23(a)(3)).

c. ***Signed statement.*** In California, a seller must obtain a signed statement from either a California-licensed physician and surgeon, audiologist, or a hearing aid dispenser verifying that the professional performed the direct observation of a purchaser's ear canals and advised the purchaser to consult with a physician upon becoming aware of the conditions outlined in "Warning to Hearing Aid Dispensers," located at 21 CFR 801.420(c)(2). ((BPC 2538.23(a)(3)). There is no federal requirement that the seller obtain such a signed statement. Rather, the "Warning to Hearing Aid Dispensers" is

[4] The Legislative history for SB 933 is not included as that legislative change only dealt with the repeal and relocation of the law at issue, the text of which was unchanged.

included in the User Instructional Brochure that accompanies the hearing aid (21 CFR 801.420(c)(2)).

d. ***Seller must retain above statement for seven years*** (BPC 2538.23(b)). Under the Federal regulations, a hearing aid dispenser shall retain copies of any written statements regarding the medical evaluation or waiver requirement for three years (21 CFR 801.421(d).

(3) Problems Addressed by BPC 2538.23

a. California law requires a license for selling hearing aids via catalog or direct mail. This requirement provides the Board with jurisdiction over catalog and mail transactions and the authority to regulate the same. This requirement was adopted to address problems with fraud and misconduct by catalog and mail sellers of hearing aids, like non-delivery or delivery of inferior product (APPENDIX E, Letter dated 7/12/90 to governor from Sen. Rosenthal). Prior to this law, the Board did not have the authority to discipline fraudulent hearing aid dispensers selling through catalog or mail. Now, the Board may investigate complaints and take appropriate disciplinary action against the catalog or mail order licensee. (APPENDIX B, p. 2; APPENDIX C, Form DF-43, p. 2; APPENDIX D, document entitled Assembly Health Committee Republican Analysis, p. 1).

b. BPC 2538.23 prohibits licensed hearing aid dispensers from rendering professional services in catalog or mail transactions to protect consumers. The fitting, adaptation, selection, or proper testing of a hearing aid, or the taking of an ear mold impression, or the giving of advice regarding the taking of an ear impression for an ear mold cannot be effectively done by a hearing aid dispenser, sight unseen, via catalog or mail order. In these cases, the hearing aid received will likely not provide the consumer with the hearing assistance that was promised or expected with respect to fit, size, and functioning. In worst cases, an improper hearing aid may actually harm the consumer. On the other hand, if a consumer purchases a hearing aid 'as is' through mail order or catalog, that consumer may then consult a hearing aid dispenser in person to address fit, size, and function, considering that consumer's particular hearing impairment.

c. California law requires examination of the prospective consumer's ear canal by a licensed: physician, audiologist, or a hearing aid dispenser, and evaluation for medical clearance for hearing aid use by a licensed physician. Allowing for a waiver of this requirement places a consumer at risk, as underlying medical conditions that result in hearing loss and which may require medical or surgical management beyond simple rehabiliation of hearing with amplification devices may go undetected. Such conditions include but are not limited to: canal atresia, canal stenosis, cerumen impaction, exostoses, otitis externa, tympanic membrane perforation, congenital ossicular chain abnormalities, acquired ossicular chain abnormalities, otosclerosis, chronic otitis media, cholesteatoma, mastoiditis with or without intracranial complications (including meningitis, brain abscess, lateral sinus thrombosis, and otitic hydrocephalus), glomus tympanicum / glomus jugulare / and other middle ear tumors. All of these conditions require medical and or surgical management, and many of these conditions are life threatening if not appropriately diagnosed and treated medically or surgically by a physician.

d. BPC 2538.23 (a)(3) requires the seller retain a signed statement from the professional who observed the prospective hearing aid user, as the signature verifies the content and validity of the document by the individual.
e. California requires that the above documentation be kept for seven years. Since the Board has no statute of limitations for prosecuting cases, a longer document retention time means that the Board may investigate older cases. The length of seven years has been determined by other health care boards to be a reasonable length of time by which to commence action. For example, the Medical Board of California, with certain exceptions, must file an accusation against a licensee within seven years after the alleged act or omission occurs. (BPC 2230.5).[5] In the hearing aid context, an act or omission subject to discipline may be evidenced by the documentation (or lack thereof) required by the statute at issue.

(4) Basis for Exemption Request

The Board relies upon the fact that its statute is more stringent than a requirement applicable to a device under federal regulation.

a. Requiring a seller to hold a hearing aid dispenser's license is more stringent than not requiring the same. The reason for this more stringent requirement is outlined in Item (3)a., above.
b. Prohibiting the rendering of professional hearing aid dispenser services for catalog or mail sales is more stringent than allowing the same. The reason for this more stringent requirement is outlined in Item (3)b., above.
c. Requiring an observation of the ear canals is more stringent than not requiring the same. The reason for this more stringent requirement is outlined in Item (3)c., above.
d. Requiring a signed statement verifying that the requirements for ear canal observation and advice to consult with a physician have been complied with is more stringent than not requiring the same. The reason for this more stringent requirement is outlined in Item (3)d., above.
e. Requiring a seller to maintain documentation for seven years is more stringent that requiring a seller to maintain the same for three years. The reason for this more stringent requirement is outlined in Item (3)e., above.

(5) Title of Officer

I, Annemarie Delmugnaio, Executive Officer of the Board, am the officer that has primary responsibility for administration of the Board's laws and regulations.

(6) Records of Administration

Upon request, the Board will furnish the FDA records concerning administration of the requirement for which the Board is seeking exemption, namely, BPC section 2538.23, to the extent allowable by law.

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[5] BPC 2230.5(a) reads, in pertinent part: "...an accusation filed against a licensee... shall be filed within three years after the board, or a division thereof, discovers the act or omission alleged as the ground for disciplinary action, or within seven years after the act or omission alleged as the ground for disciplinary action occurs, whichever occurs first."

The Board reserves the right to withhold confidential or privileged documents, or documents that are subject to non-disclosure.

(7) Public Health and Interstate Commerce

Public health will be benefitted in the manner set forth in Item 3. The Board does not believe that interstate commerce will be affected any more than commerce within California, as the bar to internet sales applies to in-state and out-of-state companies alike. Similarly, the requirement that catalog and mail order sellers be hearing aid dispensers licensed in California applies to in-state and out-of-state sellers alike.

(8) Other Pertinent Information

California has already obtained two exemptions from federal pre-emption, for BPC 2538.35 (formerly BPC 3365) and BPC 2538.37 (formerly BPC 3365.6) (21 CFR 808.55(a)).

If you have any questions on the foregoing, or need additional information, I may be reached at (916) 263-2909.

Sincerely,

Annemarie Del Mugnaio

ANNEMARIE DELMUGNAIO
Executive Officer
Speech-Language Pathology, Audiology, and Hearing Aid Dispensers Board

AIMS Correspondence System: Accept or Decline Referral

Referral to CDRH/OC/DOEA/ on Correspondence Control # 2012-4508 from CDRH/OC/

Referral Information:

Referral Date: 06/13/2012 **Action Requested:** Direct Reply **Due Date:** 07/18/2012
Remarks: NONE

Record Information:

View Orig. Corr.

Lead Office: OM/DDM/ **Home Office:** OM/DDM/ **Due Date:** 07/18/2012

View Info. Page

Recd Date: 06/05/2012 **Corr. Date:** 05/30/2012
To: DOCKETS, MANAGEMENT
From: Delmugnaio, Annemarie
Signature Level: NOT SPECIFIED
Synopsis: Application for Exemption from Pre-Emption of Device Requirement.

Accept/Decline Referral:

After reviewing the above information, CDRH/OC/DOEA/ Accepts **the referral.**

After reviewing the above information, CDRH/OC/DOEA/ Declines **the referral.**