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VIA ELECTRONIC MAIL

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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**Re: Comments to Docket No. 01N-0067
Proposed Rule: Classification of Encapsulated Amalgam Alloy
and Dental Mercury and Reclassification of Dental Mercury;
Issuance of Special Controls for Amalgam Alloy**

Dear Sir or Madam:

In addition to our comments submitted May 21, 2002,¹ in response to the proposed rule entitled “Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy,”² we submit the following comments on behalf of persons who request the action stated below by the Food and Drug Administration (“FDA”).

First, we request that the FDA classify encapsulated amalgam alloy and mercury and dental mercury as Class III devices. In classifying the devices, the FDA should review (1) research studies published in peer-reviewed journals from 1993 to the present,

¹ Comments to Docket No. 01N-0067, FDA Docket No. EMC143 (submitted May 21, 2002).

² Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy, 67 Fed. Reg. 7620 (proposed Feb. 20, 2002) (to be codified at 21 C.F.R. pt. 872).

and (2) reports received by the FDA of adverse effects from restorative materials, as was recommended by the 1993 U.S. Public Health Service Report.³

Second, we request that the FDA hold a public hearing before a public advisory committee to obtain comments on the classification process, pursuant to the FDA's regulatory mandate to obtain the "views of all segments of the public."⁴

Regardless of the outcome of the reclassification, the FDA should require postmarket surveillance of encapsulated amalgam alloy and mercury and dental mercury, pursuant to 21 C.F.R. § 822.1.⁵ The failure of the devices is reasonably likely to result in serious health consequences and the devices at issue are intended to remain in the body for more than one year.⁶ The extreme toxicity of mercury has been "well-established" and acknowledged by the Agency in the proposed rulemaking.⁷ Consequently, postmarket surveillance is appropriate because of the need for protecting the public health and preventing adverse events.⁸

³ *Id.* at 7622.

⁴ Public Hearing Before a Public Advisory Committee, 21 C.F.R. § 14.1(a)(6)(iii) (2001).

⁵ Postmarket Surveillance, 21 C.F.R. § 822.1(a), (b) (effective July 8, 2002).

⁶ *Id.*

⁷ 67 Fed. Reg. 7620, 7626.

⁸ *Id.* § 822.2.

I. BACKGROUND

The FDA proposes to (1) reclassify dental mercury from Class I to Class II with special controls; (2) amend the Class II classification of amalgam alloy to add special controls; and (3) issue a separate classification for encapsulated amalgam alloy and dental mercury.⁹ Section 513 of the Federal Food, Drug and Cosmetic Act (“FFDCA”) provides that the FDA may initiate the reclassification of devices “[b]ased upon *new information*.”¹⁰ *New information* is that “developed as a result of reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time.”¹¹ Additionally, it must consist of *valid scientific evidence*.¹² Non-valid scientific evidence may also be considered in “identifying a device the safety and effectiveness of which is questionable.”¹³

In classifying a medical device, the FDA must weigh the “probable benefits to health from use of the device against any probable risks of injury or illness from such use.”¹⁴ In the proposed rulemaking, the FDA concluded that *valid scientific evidence exists* to determine the safety and effectiveness of dental amalgam, relying primarily on reports published prior to 1998.¹⁵ The FDA based this conclusion regarding the safety of dental amalgam on the lack of persuasive evidence to the contrary,¹⁶ and only

⁹ 67 Fed. Reg. 7620.

¹⁰ Federal Food, Drug, and Cosmetic Act, Pub. L. No. 756-717, 1040 Stat. 1040 (1938) (codified at 21 U.S.C. § 301 et. seq. (1997)) (emphasis added).

¹¹ 67 Fed. Reg. 7620, 7621 (citations omitted).

¹² Medical Devices, Determination of Safety and Effectiveness, 21 C.F.R. § 860.7(c)(2) (2001). *Valid scientific evidence* consists of “well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device.” *Id.*

¹³ *Id.*

¹⁴ 67 Fed. Reg. 7620, 7626 (proposed Feb. 20, 2002) (citing § 513(a)(2) of the FFDCA).

¹⁵ *Id.*

¹⁶ In the preamble to the proposed rule, the FDA made numerous references to a 1993 report by a Committee to Coordinate Environmental Health and Related Programs (“CCEHRP”) Subcommittee on Risk Management (“PHS Report”). The PHS Report stated that “Adverse health consequences ... cannot be totally dismissed” and “The

acknowledged that “there are some risks . . . associated with improper storage, trituration, and handling of the product.”¹⁷ The Agency concluded that “the probable benefits of restorative dental products containing mercury outweigh the probable risks.”¹⁸

The fault in the Agency’s analysis is that it did not take into account all publicly available information in establishing special controls that would provide a reasonable assurance of safety, and thus should reclassify encapsulated amalgam alloy and mercury and dental mercury as Class III until the safety of dental mercury can be proven by valid scientific evidence in accord with FDA administrative policy.

II. RECOMMENDATIONS

A. Dental Amalgam Products Warrant Classification as Class III

First, we request that the FDA reclassify encapsulated amalgam alloy and mercury and dental mercury as Class III because the lack of “persuasive evidence that the physiological and psychological symptoms attributed to amalgam fillings are caused by amalgam fillings” is *not* the same as evidence supporting the safety of dental amalgam.¹⁹ Therefore, the FDA should not use a lack of scientific evidence to justify the contention that “valid scientific evidence exists to determine the safety and effectiveness of dental amalgam.”²⁰

1. The FDA’s Review of Scientific Studies Was cursory and Outdated

A defect in the FDA’s preparation of the proposed rule is that the Agency did not evaluate peer-reviewed scientific studies published after 1993. While the Agency cites

(Footnote cont'd from previous page.)

potential for effects at levels of exposure produced by dental amalgam restorations has not been fully explored.” *Id.* at 7622 (proposed Feb. 20, 2002).

¹⁷ *Id.* at 7627.

¹⁸ *Id.* at 7627.

¹⁹ *Id.* at 7626.

²⁰ *Id.*

domestic and international reviews on the issue, it does not evaluate any studies published in peer-reviewed journals after 1993.²¹

2. The FDA Did Not Consider All Risks and Benefits Associated With Dental Amalgam and Mercury Products

In balancing the risks and benefits associated with the use of encapsulated amalgam alloy and mercury and dental mercury, the FDA did not give full consideration to recommendations of other countries, nor did the Agency acknowledge that in past situations regarding certain products, such as silicon breast implants and thimerosal in vaccines, the Agency has acted—despite a lack of valid scientific evidence—as a “precautionary measure.”²²

3. The FDA’s Special Controls Will Not Sufficiently Protect Against the Dangers of Dental Amalgam and Mercury

In the “Special Control Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Draft Guidance for Industry and FDA” (“Draft Guidance”), the FDA delineates guidance for manufacturers to comply with the special controls on dental amalgam under Class II. The Draft Guidance addresses labeling, handling, storage, and warning requirements.²³

Additionally the FDA has proposed to include the International Organization for Standardization, 1559:1995 Dental Materials – Alloys for Dental Amalgam²⁴ describing specifications test methods for alloys used in amalgam, handling, storage, packaging and

²¹ See *id.* at 7623-24.

²² *Thimerosal in Vaccines*, U.S. Food and Drug Administration, <http://www.fda.gov/cber/vaccine/thimerosal.htm> (last visited June 11, 2002).

²³ Draft Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Availability, Food and Drug Administration, 67 Fed. Reg. 7703 (proposed Feb. 20, 2002), available at <http://www.fda.gov/cdrh>.

²⁴ ISO 1559:1995 Dental Materials – Alloys for Dental Amalgam, International Organization for Standardization, <http://www.iso.org/iso/en/CatalogueDetailPage.CatalogueDetail?CSNUMBER=6149&ICS1=11&ICS2=60&ICS3=10> (last visited June 28, 2002).

labeling instructions, and ANSI/ADA's "Specification No. 6-1987 for Dental Mercury," which addresses similar issues, as part of the special controls.²⁵

The above special controls are inadequate to prevent the actual leakage of "minute amounts of elemental mercury, a metal whose toxicity at high exposure levels is well-established."²⁶ Informing the public and protecting the public interest are not the same in the situation at hand. As detailed in our earlier comments, other countries such as Canada, Sweden, Germany, and Norway have acknowledged that while there is no direct link between dental mercury and illness, there is a risk large enough to prompt those countries to enact precautionary measures relating to actual use in certain patients and proposed research plans to evaluate the effects of the devices;²⁷ so should the FDA promulgate regulations regarding actual use, rather than mere packaging and handling requirements, in order to better fulfill the Agency's mandate of protecting the public health.

B. A Public Hearing Before a Public Advisory Committee Would Ensure the Public Interest is Served

In addition to reclassifying the devices into Class III, we request that the FDA hold a public hearing before a public advisory committee to obtain comment on the classification of dental mercury and encapsulated amalgam alloy and mercury.²⁸ The FDA is authorized to hold hearings on a proposed or final regulation under 21 C.F.R. § 10.40.²⁹ The Agency should do so in this case under 21 C.F.R. § 14.1(a)(2)(vi), which permits the Commissioner to hold a hearing before a public advisory committee in the public interest on the classification of devices.³⁰

²⁵ Specification No. 6-1987 for Dental Mercury, American National Standards Institute, <http://www.ansi.org> (last visited June 28, 2002).

²⁶ 67 Fed. Reg. 7620, 7626 (proposed Feb. 20, 2002).

²⁷ See Comments to Docket No. 01N-0067, FDA Docket No. EMC143 (submitted May 21, 2002).

²⁸ 21 C.F.R. § 14.1 (2001).

²⁹ Promulgation of Regulations for the Efficient Enforcement of the Law, 21 C.F.R. § 10.40(f) (2001).

³⁰ 21 C.F.R. § 14.1 (2001).

It is the duty of the Agency to seek out “the views of all segments of the public on enforcement of the laws administered by the Commissioner.”³¹ In the proposed rule the FDA repeatedly stressed “heightened public concern” as a primary reason for reevaluating the safety of encapsulated amalgam alloy and mercury and dental mercury.³² A public hearing on this matter would ensure that the concerns of the public are taken into account in the reclassification process.

C. The FDA Should Require Postmarket Surveillance Under 21 C.F.R. Pt. 822

Finally, regardless of the outcome of the classification, the FDA should require postmarket surveillance of encapsulated amalgam alloy and mercury and dental mercury pursuant to 21 C.F.R. pt. 822.³³ Once reclassified as either Class II or Class III, the FDA may order postmarket surveillance of a device if: “(a) the failure of the device would be reasonably likely to have serious adverse health consequences; (b) the device is intended to be implanted in the human body for more than 1 year; or (c) the device is intended to be used outside a user facility to support or sustain life.”³⁴ “Serious adverse health consequences” are defined as “any significant adverse experience related to a device” and include events that are life-threatening or that result in “permanent or long-term injuries or illnesses.”³⁵

The FDA should order postmarket surveillance of encapsulated amalgam alloy and mercury and dental mercury under (a) or (b) above because (1) there is a risk of mercury poisoning from dental amalgam, as the FDA acknowledged in this rulemaking, or (2) the device is intended to be used in the body for more than one year.

³¹ *Id.* § 14.1(b)(6)(iii).

³² 67 Fed. Reg. 7620, 7621 (proposed Feb. 20, 2002).

³³ 21 C.F.R. pt. 822 (effective July 8, 2002).

³⁴ *Id.* § 822.1.

³⁵ *Id.* § 822.3(j).

The purpose of the part is to “maximize . . . the collection of useful data,” which can “reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.”³⁶ The Agency stated in the preamble to the proposed rule that valid scientific evidence *exists* to support the safety of dental amalgam despite the fact that the scientific evidence cited by the Agency is equivocal and neither supports nor refutes the position that exposure to mercury from dental amalgam is toxic.³⁷ This contradictory statement gives the FDA further reason to order postmarket surveillance, so that data may be collected and added to the existing record of the seriousness of this public health risk.

D. State Restrictions are Indicative of the Public’s Concern and are Not in Conflict With or in Addition to FDA Regulations

The Agency did not address preemption concerns in the proposed rulemaking, but we believe the matter should be addressed. Several states have passed legislation regulating or prohibiting the use of mercury in various products for environmental and health reasons. Many states require that patients be educated by dental professionals about the risks of dental mercury and alternative treatments or prohibit the sale of products containing mercury.³⁸ In addition, a bill pending in the U.S. Congress would require that mercury cease to be used in dental fillings as of January 1, 2007, and that products contain a warning during the transitional period.³⁹ Both the state and federal legislation are yet another indication of the public’s concern about the dangers of dental mercury and further reason to hold a public hearing to seek out the “views of all segments of the public.”⁴⁰

³⁶ *Id.* § 822.2.

³⁷ 67 Fed. Reg. 7620, 7626 (proposed Feb. 20, 2002).

³⁸ *See, e.g.*, H.R. 1251, 157th Leg., 2002 Sess. (N.H. 2002) (requiring distribution of standardized pamphlet and discussion of alternative treatments with patients) (enacted); H.R. 1252, 120th Leg., 1st Sess. (Me. 2000) (requiring poster to be displayed and brochure developed discussing risks of dental mercury) (enacted); S. 633, 2001-2002 Sess. (Cal. 2001) (prohibiting the sale of certain products containing mercury) (enacted).

³⁹ Mercury in Dental Filling Disclosure and Prohibition Act, H.R. 4163, 107th Cong. (2002).

⁴⁰ 21 C.F.R. § 14.1 (2001).

Section 521 of the FFDCFA provides for express preemption of state requirements regarding medical devices that are “(1) different from, or in addition to, any requirement under this Act . . . and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.”⁴¹ A state may, however, request an exemption if the state requirement is (1) more “stringent” than any requirement under the FFDCFA, or (2) “required by compelling local conditions” and “compliance with the requirement would not cause the device to be in violation of any applicable requirement” under the FFDCFA.⁴²

1. Prohibitions on the Sale of Products With Mercury Qualify as “More Stringent” and are Not Preempted

State regulations that prohibit the sale of products containing mercury are more stringent than the federal requirements and thus may qualify for exemption under § 521(b)(1) of the FFDCFA. The Supreme Court recently denied certiorari in a case where the Second Circuit Court of Appeals had denied an appeal of lamp manufacturers protesting the constitutionality of a state labeling requirement that manufacturers must inform users that a product contains mercury.⁴³ The Second Circuit noted that Congress “expressly [left] individual states with flexibility to adopt regulations more stringent than those imposed by the federal government” in the statute involved, as in the FFDCFA.⁴⁴ Prohibition of the use of dental mercury is certainly a more stringent requirement than the proposed rule on classification and special controls and should not be preempted.

2. State Informational Requirements Do Not Interfere With Applicable Regulations Under the FFDCFA and are Not Preempted

Additionally, under § 521(b)(2), states are permitted to regulate in an area covered by the FFDCFA if they do so for compelling local reasons and if compliance would not

⁴¹ FFDCFA § 521(a).

⁴² *Id.* § 521(b).

⁴³ Nat’l Elec. Mfrs. Ass’n v. Sorrell, Attorney Gen. of Vt., No. 99-9450 (2d Cir. 2001), *cert. denied*, No. 01-1489 (June 10, 2002).

⁴⁴ *Id.*

interfere with the provisions of or regulations under the FFDCA.⁴⁵ Most state statutes either prohibit the use of mercury in products or require that dentists inform patients through brochures or posters about possible dangers. Thus far, Vermont is the only state to have required labeling of mercury-containing products and, as discussed above, the Supreme Court has denied *certiorari* in that case, thus allowing the statute to stand.⁴⁶

Compliance with state requirements that dentists give patients information about the risks of dental mercury through posters or brochures does not interfere with the proposed rule and special controls, which deal primarily with the classification, labeling, handling, and storage of encapsulated amalgam alloy and mercury and dental mercury. Further, it has been firmly established that the states may legislate for the health and safety of their citizens, as they have done here.⁴⁷

3. Certain Other State Requirements Pertaining to Dental Mercury are Not Preempted

State or local requirements are only preempted when the FDA has “established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements . . . different from, or in addition to, the specific [FDA] requirements.”⁴⁸ Certain requirements are not preempted, however, such as where the state or local requirements are “equal to, or substantially identical to, requirements imposed by or under the act,” or the requirements pertain to “permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of . . . dentistry,” among others.⁴⁹

⁴⁵ FFDCA § 521(b)(2).

⁴⁶ See Nat'l Elec. Mfrs. Ass'n v. Sorrell, Attorney Gen. of Vt., No. 99-9450 (2d Cir. 2001), *cert. denied*, No. 01-1489 (June 10, 2002).

⁴⁷ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (citing *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719 (1985); *Metropolitan Life Ins. Co. v. Mass.*, 471 U.S. 724, 756 (1985)).

⁴⁸ 21 C.F.R. § 808.1(d) (2001).

⁴⁹ *Id.*

For example, California's licensing requirements for dentists require that the patient be provided with materials discussing potential health risks before undergoing an oral procedure, which clearly falls under § 808.1(d) and should not be preempted.⁵⁰ California also requires that the Directions For Use of mercury-containing dental capsules carry a notice that such products are "known by the state of California to cause birth defects or other reproductive harm." In addition, the contraindications listed in the Directions for Use, including that the "use of amalgam is contraindicated . . . [i]n children 6 and under" and "[i]n expectant mothers," are further indications of the public's concern about mercury-containing dental compounds.

The proposed rule and specific controls relate only to the classification, marketing, and labeling of the device itself, not to any guidance literature produced by the state pertaining to the practice of dentistry or the complete prohibition of the product.

III. CONCLUSION

For the reasons stated above, we request that the FDA (1) classify encapsulated amalgam alloy and dental mercury as Class III devices, (2) hold a public hearing before a public advisory committee to obtain comments from interested segments of the public, (3) require postmarket surveillance of the devices, and (4) address the possible preemption of state requirements. Further, the FDA should consider the range of the responses of states and localities as evidence of the public's concern and the need for public debate on this matter.

Respectfully submitted,



Stuart Kim

⁵⁰ S. 134, 2001-2002 Sess. (Cal. 2001) (enacted).