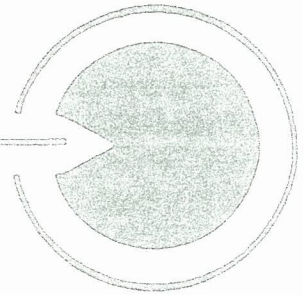


# BIO-PROBE

# NEWSLETTER



Vol. 18, Issue 6

Bio-Probe Newsletter

November 2002

## Is the FDA [Dental Devices Division] Confused On Dental Amalgam?

\*Is Dental Amalgam an approved Class II device?

\*Is Dental Amalgam, by rule, a Class III device?  
\*\*\*

Who knows? The FDA doesn't seem to know! If you were to call the Dental Division of the FDA (and please do: 301-827-5283), they will tell you that FDA has approved Dental Amalgam as a Class II device. However, and this is a BIG however, they cannot provide any documentation to support that position. There is **no** notification of approval, **no** 510K, **no** classification of dental amalgam in the Federal Register, **no** placement in the FDA listing of approved dental devices.

Others say that, because dental amalgam is a widely used dental device that a previous FDA Commissioner refused to exempt from its definition of 'implant', it automatically becomes a Class III device until it can be reclassified by evaluation according to FDA Rules.

The time has come for everyone to **demand** explanations from FDA for their conduct! Only public demand and pressure from the United States Congress will oblige FDA to publicly stand responsible for their actions on dental amalgam.

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The documented facts: FDA on Amalgam

### Table of Contents

FDA: Who Are You Working For? .....	1
The Documented Facts: FDA on Amalgam .....	1
Two Major Legal Victories Against Dental Amalgam .....	3
Daubert Ruling .....	3
Frye Ruling .....	6
Belgium Bans Fluoride Supplements .....	7

### SCIENCE

Effects of Continuous Low-Dose Exposure to Organic and Inorganic Mercury -Epileptogenicity. Szasz, A, et al .....	7
Effects of Metals on the Nervous System of Humans and Animals. Carpenter, DO .....	7
Disposition of Inhaled Mercury Vapor in Pregnant Rats: Maternal Toxicity and Effects, etc. Morgan, et al .....	8

### FORUM

IAOMT 2003 Mid-Year Meeting.....	8
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- In 1976, the President and the Congress of the United States directed FDA to evaluate all medical (including dental) devices intended for human use and to classify them according to their safety and effectiveness. [FR 41(157):34099, 12 Aug 1976] To this day, "Dental Amalgam" is not listed as an accepted

and classified dental device, even though it been the most widely utilized of all dental devices. **WHY?**

- FDA has ruled that mercury is not GRAS (Generally Recognized to be Safe). [FR 63(77): 19799-19802, 22 Apr 1998] Yet, the FDA Dental Device Division accepted and classified "Dental Mercury" as a Class I safe and effective dental device. [FR 52(155):30082-30108, 12 Aug 1987] **WHY?**
- FDA accepted and classified "Amalgam Alloy" as a Class II safe and effective dental device [FR 52(155):30082-30108, 12 Aug 1987], knowing full well that amalgam alloy is a powder that will immediately wash out of a dental cavity. **WHY ?**
- In 1978, the FDA Dental Device Panel requested that dental amalgam be exempted from the FDA Rule definition for "implant" ("*a device that is placed into surgically or naturally formed cavities of the human body.*" [FR 42(177):46035, 13 Sep 1977]) The FDA Commissioner denied that request [FR 43(146):32988, 28 Jul 1978] Yet, the FDA Dental Device Panel ruled that dental amalgam was not an implant, in direct contradiction to the ruling of the FDA Commissioner. [FR 45(251):85964, 30 Dec 1980] **WHY?**
- FDA Rules clearly define acceptable evidence in determining safety and effectiveness of devices [FR 43(146):32988-32999, 28 Jul 1978], expressly excluding "*random experience, reports lacking the details to permit scientific evaluation, or unsubstantiated opinion*" as acceptable. [Pg. 32995] Further, FDA Rules define the "valid scientific evidence" required to accept devices. [Pg. 32990-32996] Yet the Dental Division of FDA violated FDA Rules in accepting "Dental Mercury" and "Amalgam Alloy" as safe and effective dental devices,

without providing valid scientific documentation as required by FDA Rules.

**WHY?**

- FDA Rules further state: "*Although no device can be regulated adequately in Class I or Class II unless there are adequate data and information establishing its safety and effectiveness, a device for which there are such data and information may nevertheless require regulation in Class III because of the public health concerns posed by its use.*" [FR 42(177):46030, 13 Sep 1977] The Dental Device Division clearly violated this requirement in their final ruling in 1987. [FR 52(155):30082-30108, 12 Aug 1987] **WHY?**

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This brings us to current activities of the FDA on mercury, specifically dental amalgam mercury.

FDA, on 20 February 2002, announced a 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." With this, FDA's only intention is to reclassify Dental Mercury into Class II and accept a "capsule" containing dental mercury on one side and amalgam alloy on the other as a "safe and effective" dental device.

**Questions:** Are any of these three devices actually inserted into the patient? Are any of the three, by themselves, "effective" as dental devices? The answer is obviously NO! Therefore, FDA acceptance of the three is a patent violation of their own rules.

**Questions:** Why does FDA recall products, such as shark and swordfish, for containing "excessive amounts of mercury" while deeming a daily exposure to mercury from amalgam dental fillings to be "safe" for humans? Does FDA really expect the public, and the United States Congress, to accept their position that an extremely rare exposure to shark or swordfish mercury is more