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U. S. Food and Drug Administration (USFDA)  
Dental Devices Branch  
Office of Device Evaluation

Docket No. 01N-0067

Comment Position: Against proposal to classify Encapsulated Amalgam as an accepted Class II Dental Device, as a violation of USFDA Rules.

USFDA Rules define an "implant" as *"a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health."* [FR 43(146):32994, 860.3 (d), 28 July 1978]. In 1978 the Food and Drug Administration Commissioner refused to exclude mercury/silver amalgam dental fillings from its definition as an implant. [FR 43(146):32988, 28 July 1978]

USFDA Rule 860.93 (a) requires implants to be placed into Class III for Premarket Approval unless the requirements of Rule 860.7 are satisfied. [FR 43(146):32997, 28 July 1978] USFDA Rule 860.7 states: *"The agency relies upon only valid scientific evidence to determine whether there is a reasonable assurance that the device is safe and effective."*; and *"Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety and effectiveness."* [FR 43(146):32995, 28 July 1978]

In its current proposal to classify dental amalgam [FR 67(34):7620-7630, 20 February 2002], USFDA acknowledges potential risks of exposure to mercury from dental amalgam or insufficient information to determine risks or lack of risks. [p. 7621, III; p. 7622, A, (2)(3)(4); p. 7623, D (2); p. 7625, E; p. 7626-7] Clearly, USFDA would be in violation of its own Rules unless dental amalgam were placed in Class III, requiring Premarket Approval.

Comment Position: Against proposed reclassification of Dental Mercury to Class II as a safe and effective dental device. This is directly contradictory to USFDA position on mercury.

In 1998, USFDA ruled that mercury and its compounds are NOT Generally Recognized As Safe (GRAS) and eliminated them from Over The Counter (OTC) products. [FR 63(77):19799-19802, 22 April 1998] By first accepting Dental Mercury as a Class I safe and effective dental device and now proposing acceptance into Class II, USFDA is acting contradictory to its own precedent. Is USFDA taking the position that Dental Mercury is the only non-toxic form of mercury known?

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Comment Position: Against USFDA's failure to require consumer notification of the ingredients in dental amalgam (Full Disclosure). In its Proposed Rules [FR 67(34):7620-7630, 20 February 2002], USFDA states "*the clinician would be made aware of all materials he/she is placing*" (p. 7627) and "*FDA is recommending a consistent label that will allow interested consumers of dental amalgam to easily obtain necessary information that may result in mercury exposure avoidance.*" (P. 7628) Yet, even though mercury is scientifically acknowledged to be highly toxic and USFDA acknowledges consumer exposure to amalgam mercury, the Guidance Document contains no requirement that the consumer be provided with Full Disclosure. This omission is clearly not in the best interest of protection of the consumer, nor in protection of clinicians from potential medico-legal jeopardy. USFDA requires that the clinician be informed, which is actually the responsibility of OSHA and NIOSH. The responsibility of USFDA is to the consumer.

On behalf of the *International Academy of Oral Medicine and Toxicology*,



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Executive Director