

DATES: Submit written or electronic comments by March 1, 2004. See section X of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283, ext. 123, mea@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The act (21 U.S.C. 301 *et seq.*), as amended by the Medical Devices Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the SMDA (Public Law 101-629), and FDAMA (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are as follows:

- Class I (general controls),
- Class II (special controls), and
- Class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as preamendments devices. Under the 1976 amendments, class II devices are identified as those devices in which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but for which there is sufficient information to establish a performance standard to provide such assurance.

The SMDA broadened the definition of class II devices to include those devices for which general controls would not provide reasonable assurance of the safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance. The special controls include performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other

appropriate actions the agency deems necessary to provide such assurance. See section 513(a)(1)(B) of the act.

FDAMA added, among other sections, a new section 510(m) to the act (21 U.S.C. 360(m)). Under new section 510(m) of the act, FDA may exempt a class II device from premarket notification requirements (510(k)) (21 U.S.C. 360(k)), if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

II. Regulatory History of the Devices

In the **Federal Register** of August 12, 1987 (52 FR 30082), FDA issued a final rule classifying 42 dental devices into class II, including gold-based alloys and precious metal alloys for clinical use and base metal alloy under the 1976 amendments.

III. Proposed Rule

FDA is proposing to amend the classification regulation of gold-based alloys and precious metal alloys for clinical use and base metal alloy devices in order to designate a special control for these devices. These devices were classified before the provisions of the SMDA broadened the definition of class II devices to establish special controls beyond performance standards and before the SMDA regulations became effective. Therefore, designating device-specific guidance as a means to provide reasonable assurance of the safe and effectiveness of the device was not a regulatory option at the time. Since the classification, FDA has not developed a performance standard for these devices.

FDA has now developed guidance documents for these devices and, under the SMDA provisions, is proposing to designate the special controls the agency believes will reasonably assure the safety and effectiveness of these devices. FDA is identifying the guidance documents entitled "Class II Special Controls Guidance Document: Dental Precious Metal Alloys" and "Class II Special Controls Guidance Document: Dental Base Metal Alloys" as the proposed special control for precious metal alloys (including gold based) and base metal alloys, respectively. Following the effective date of any final classification rule based on this proposed rule, any firm claiming exemption from the premarket notification requirements for a dental precious metal or base metal alloy covered by the rule will need to address the issues covered in the appropriate special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides

equivalent assurances of safety and effectiveness.

Under section 510(m)(1) of the act, FDA is also proposing to exempt these devices from premarket notification. The agency has determined that a 510(k) is not necessary to assure the safety and effectiveness of these devices.

IV. Risks to Health

FDA has identified the following risks to health associated with these devices: Device failure, adverse tissue reaction, and improper use.

A. Device Failure

The mechanical properties of precious and base metal casting alloys, and solders and porcelain-fused-to-metal (PFM) alloys may be insufficient to support the required loads and lead to device failure. Some alloy compositions used in base metal casting alloys and solders, may be susceptible to corrosion, which can lead to device failure. Porcelain in PFM alloys may deform, crack, and debond from the metal because of incompatibilities leading to device failure. Device failure will result in ineffective treatment, revision, and possibly minor, temporary impairment for the patient.

B. Adverse Tissue Reaction

Some alloy compositions, especially those containing nickel, as pertaining to base metal casting alloys and solders, may not be biocompatible. Poor biocompatibility may result in adverse tissue reaction.

C. Improper Use

Inadequate labeling may result in improper use. Improper use may result in ineffective treatment and may cause minor temporary impairment for the patient.

V. Special Controls

FDA believes that, in addition to general controls, the class II special controls guidance documents entitled "Class II Special Controls Guidance: Dental Precious Metal Alloys" and "Class II Special Controls Guidance Document: Dental Base Metal Alloys" are adequate controls to address the risks to health described in section IV of this document. The class II special controls guidance documents provide information on how to control the risks to health of device failure, adverse tissue reaction, and improper use, by identifying FDA-recognized consensus standards and labeling that will mitigate risks to health included in the guidances.

The consensus standards provide minimum mechanical properties to