

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 2003N-0390]

Dental Devices; Gold Based Alloys, Precious Metal Alloys, and Base Metal Alloys; Designation of Special Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the classification regulations of gold-based alloys and precious metal alloys for clinical use and base metal alloy devices. FDA is also proposing to exempt these devices from premarket notification and designate a special control for these devices. The agency is taking this action on its own initiative. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of guidance documents that would serve as special controls for these devices.

DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the Federal Register*]. 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,

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Display Date
Publication Date
Certifier Sheese

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 address the risks of device failure. Adherence to the recommended standards

can mitigate the risk of device failure, e.g., PFM deforming, cracking, or debonding because of biocompatibility.

Another consensus standard identified in the special controls guidance recommends biocompatibility testing. Adherence to this standard can mitigate the risk of adverse tissue reaction by ensuring that the device materials are sufficiently biocompatible for use as permanent implants.

The labeling information provided in the guidance documents addresses the risk of improper use by recommending that manufacturers, in addition to complying with the general labeling provisions of 21 CFR part 801, include indications for use and contraindications for individuals with nickel hypersensitivity in their labeling.

FDA believes that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of these devices and, therefore, is giving notice of its intent to exempt the devices from that requirement if the recommendations of the special controls guidance are met.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft guidance documents that would serve as the special controls for these devices.

VI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive

Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The purpose of this proposed rule is to designate a special control for these devices. FDA has designated guidance documents as the special controls. FDA believes that manufacturers, including small manufacturers, are already substantially in compliance with the recommendations in the guidance documents and they will not add substantially to the information manufacturers presently submit. FDA, therefore, believes that the rule will impose no significant economic impact on any small entities. The agency, therefore, certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

IX. Submission of Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this proposed rule. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. Proposed Implementation Plan

FDA proposes that any final regulation that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**. Following the effective date of a final rule exempting the device, manufacturers of dental precious metal alloy and base metal alloy devices will need to address the issues covered in these special controls guidances. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. If manufacturers cannot comply with these recommendations or equivalent measures, they will not be exempt from the requirements of premarket notification and will need to submit a premarket notification and receive clearance for their device prior to marketing.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 872 be amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.1 is amended by revising paragraph (e) to read as follows:

§ 872.1 Scope.

* * * * *

(e) Guidance documents in this part may be obtained on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

3. Section 872.3060 is amended by revising paragraph (b) to read as follows:

§ 872.3060 Gold-based alloys and precious metal alloys for clinical use.

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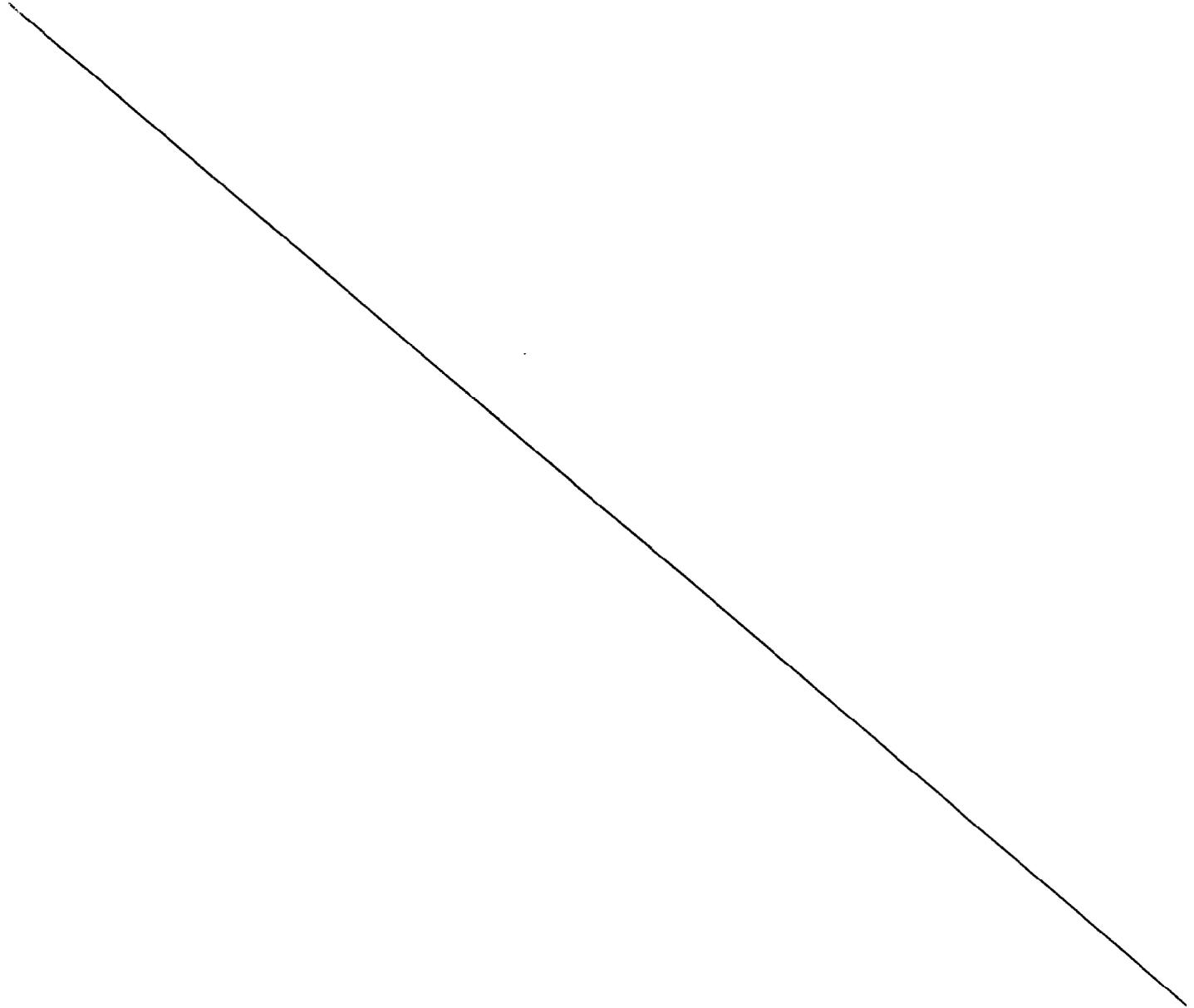
(b) *Classification.* Class II (special controls). The special control for these devices is FDA's "Class II Special Controls Guidance Document: Dental Precious Metal Alloys." The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. (See § 872.1(e) for availability of guidance information.)

4. Section 872.3710 is amended by revising paragraph (b) to read as follows:

§ 872.3710 Base metal alloy.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Dental Base Metal Alloys.” The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. (See § 872.1(e) for availability of guidance information.)



Dated: 10/2/03
October 2, 2003.

Linda S. Kahan

Linda S. Kahan,
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Center for Devices and Radiological Health.

S [FR Doc. 04-³????? Filed ??-??-04³; 8:45 am]

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