CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. Section	Description of Violation	Current Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment[1]	Adjusted Maximum Penalty Amount (in dollars)
(3) 333(b)(3)	Violation of certain requirements of the PDMA	100,000	Per violation	----	110,000
(4) 333(f)(1)(A)	Violation of certain requirements of the Safe Medical Devices Act (SMDA)	15,000	Per violation	----	15,000
(5) 333(f)(1)(A)	Violation of certain requirements of the SMDA	1,000,000	For the aggregate of violations	----	1,100,000
(6) 333(f)(2)(A)	Violation of certain requirements of the Food Quality Protection Act of 1996 (FQPA)	50,000	Per individual	----	55,000
(7) 333(f)(2)(A)	Violation of certain requirements of the FQPA	250,000	Per ''any other person''	----	275,000
(8) 333(f)(2)(A)	Violation of certain requirements of the FQPA	500,000	For all violations adjudicated in a single proceeding	----	550,000
(9) 335b(a)	Violation of certain requirements of the Generic Drug Enforcement Act of 1992 (GDEA)	250,000	Per violation for an individual	----	275,000
(10) 335b(a)	Violation of certain requirements of the GDEA	1,000,000	Per violation for ''any other person''	----	1,100,000
(11) 360pp(b)(1)	Violation of certain requirements of the Radiation Control for Health and Safety Act of 1968 (RCHSA)	1,000	Per violation per person	----	1,000
(12) 360pp(b)(1)	Violation of certain requirements of the RCHSA	300,000	For any related series of violations	----	325,000
(b) 42 U.S.C.					
(1) 263b(h)(3)	Violation of certain requirements of the Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Act of 1998	10,000	Per violation	----	10,000
(2) 300aa–28(b)(1)	Violation of certain requirements of the National Childhood Vaccine Injury Act of 1986	100,000	Per occurrence	----	110,000

[1] Dates to-be-determined by the effective date of a final rule.

Dated: October 11, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29741 Filed 11–28–03; 8:45 am]

BILLING CODE 4160–01–S

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 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 wil 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.

* * * * *

(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.

* * * * *

(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: October 2, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–29739 Filed 11–28–03; 8:45 am]

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DEPARTMENT OF THE TREASURY

31 CFR Part 50

RIN 1505–AB07

Terrorism Risk Insurance Program; Initial Claims Procedures

AGENCY: Departmental Offices, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of the Treasury (Treasury) is issuing this proposed rule as part of its implementation of Title I of the Terrorism Risk Insurance Act of 2002 (the Act). That Act established a temporary Terrorism Risk Insurance Program (Program) under which the Federal Government will share the risk of insured loss from certified acts of terrorism with commercial property and casualty insurers until the Program sunsets on December 31, 2005. This proposed rule contains procedures for filing claims for payment of the federal share of compensation for insured losses under the Program and incorporates statutory conditions for federal payment. In particular, the proposed rule addresses requirements for loss certification and associated recordkeeping requirements; provides guidance on what is payable as the federal share of insured losses; and sets forth requirements for investigating and auditing claims under the Program. The rule generally builds upon previous interim guidances and final rules issued by Treasury, particularly in areas involving definitions and disclosure requirements. This proposed rule is the fourth in a series of regulations Treasury has issued to implement the Act.

DATES: Written comments may be submitted on or before December 31, 2003.

ADDRESSES: Submit comments by e-mail to *triacomments@do.treas.gov* or by mail (if hard copy, preferably an original and two copies) to: Terrorism Risk Insurance Program, Public Comment Record, Suite 2100, Department of the Treasury, 1425 New York Ave., NW., Washington, DC 20220. All comments should be captioned with ''Proposed Rule on Claim Procedures''. Please include your name, affiliation, address, e-mail address and telephone number in your comment. Comments will be available for public inspection by appointment only at the Reading Room of the Treasury Library. To make appointments, call (202) 622–0990 (not a toll-free number).

FOR FURTHER INFORMATION CONTACT: David Brummond, Legal Counsel; Howard Leikin, Senior Insurance Advisor; C. Christopher Ledoux, Senior Attorney; Terrorism Risk Insurance Program (202) 622–6770 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

On November 26, 2002, the President signed into law the Terrorism Risk Insurance Act of 2002 (Pub. L. 107–297, 116 Stat. 2322) (the Act). The Act was effective immediately. The Act's purposes are to address market disruptions, ensure the continued widespread availability and affordability of commercial property and casualty insurance for terrorism risk, and to allow for a transition period for the private markets to stabilize and build capacity while preserving State insurance regulation and consumer protections.

Title I of the Act establishes a temporary federal program of shared public and private compensation for insured commercial property and casualty losses resulting from an act of terrorism which, as defined by the Act, is certified by the Secretary of the Treasury, in concurrence with the Secretary of State and the Attorney General. The Act authorizes Treasury to administer and implement the Terrorism Risk Insurance Program (the Program), including the issuance of regulations and procedures. The Program provides a three-year federal reinsurance backstop for insured losses from an act of terrorism until the Program ends on December 31, 2005.

Each entity that meets the Act's definition of insurer (well over 2000 firms) must participate in the Program. The amount of federal payment for an insured loss resulting from an act of terrorism is to be determined, based upon the insurance company deductibles and excess loss sharing with the Federal Government, as specified by the Act and the implementing regulations. An insurer's deductible increases each year of the Program, thereby reducing the Federal Government's share of compensation for insured losses each year until the Program expires. An insurer's deductible is calculated based on the value of direct earned premiums collected over certain statutory periods. Once an insurer has met its individual deductible, the federal payments cover 90 percent of the insured losses above the deductible, subject to an industry-aggregate limit of $100 billion.

The Act gives Treasury authority to recoup federal payments made under the Program through policyholder surcharges, up to a maximum annual limit. The Act reduces the Federal share of compensation for insured losses that have been covered under any other federal program. The Act also contains provisions designed to manage litigation arising from or relating to a certified act of terrorism. Section 107 of the Act creates an exclusive federal cause of action, provides for claims consolidation in federal court, and contains a prohibition on federal payments for punitive damages under the Program. The Act provides the United States with the right of subrogation with respect to any payment or claim paid by the United States under the Program.

II. Previous Rulemaking

This proposed rule is the latest in a series of rules issued by Treasury under the Act. In implementing the Program, Treasury has sought to achieve several goals. First, an effort has been made to implement the Act in a transparent and effective manner that treats comparably those insurers required to participate in the Program and that provides necessary information to policyholders in a useful and efficient manner. Second, Treasury seeks to rely as much as possible on the State insurance regulatory structure. In that regard, Treasury is closely coordinating with the National Association of Insurance Commissioners (NAIC) in implementing all aspects of the Program. Third, to the extent possible within statutory constraints, Treasury seeks to allow insurers to participate in the Program in a manner consistent with their normal course of business. Finally, given the temporary and transitional nature of the Program, Treasury is guided by the Act's goal for insurers to develop their own capacity, resources and mechanisms for terrorism risk insurance coverage when the Program expires.

To assist insurers, policyholders and other interested parties in complying with immediately applicable and time-sensitive requirements of the Act prior to the issuance of regulations, Treasury issued interim guidance in four separate notices on December 3 and 18, 2002 and on January 22 and March 25, 2003. Treasury publicly released these interim guidance notices on its Program Web site *http://www.Treasury.gov/trip* and published each notice in the **Federal Register** [67 FR 76206 (December 11,