

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 <sup>1</sup>	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

<sup>1</sup> 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.