Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. 2003N–0308]

Civil Money Penalties Hearings; Maximum Penalty Amounts and Compliance With the Federal Civil Penalties Inflation Adjustment Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing a new regulation to adjust for inflation the maximum civil money penalty amounts for the various civil money penalty authorities within our jurisdiction. We are taking this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), as amended.

DATES: Submit written or electronic comments by February 17, 2004.

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: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Why Are We Revising Our Civil Money Penalty Rules?

In general, the FCPIAA (28 U.S.C. 2461, as amended by the Debt Collection Improvement Act of 1996) requires Federal agencies to issue regulations to adjust for inflation each civil monetary penalty provided by law within their jurisdiction. The FCPIAA directs agencies to adjust the civil monetary penalties by October 23, 1996, and to make additional adjustments at least once every 4 years thereafter. The adjustments are based on changes in the cost of living, and the FCPIAA defines the cost of living adjustment as:

> * * * the percentage (if any) for each civil monetary penalty by which—
>
> (1) the Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds
>
> (2) the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law.

The FCPIAA also prescribes a rounding method based on the amount of the calculated increases, but states that the initial adjustment of a civil monetary penalty may not exceed 10 percent of the penalty.

The FCPIAA defines a civil monetary penalty as:

> * * * any penalty, fine, or other sanction that—
>
> (A)(i) is for a specific monetary amount as provided by Federal law; or
>
> (ii) has a maximum amount provided for by Federal law; and
>
> (B) is assessed or enforced by an agency pursuant to Federal law; and
>
> (C) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal Courts * * *.

Congress enacted the FCPIAA, in part, because it found that the impact of civil monetary penalties had been reduced by inflation and that reducing the impact of civil monetary penalties had weakened their deterrent effect.

We have identified 14 civil monetary penalties that fall within our jurisdiction and are subject to adjustments under the FCPIAA. The following table lists those penalties, their maximum penalty amounts, assessment methods, the dates that the penalties were last set or adjusted, and the adjusted penalty amount. The affected civil monetary penalties provisions are sections 303, 307, and 539 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 333, 335b, and 360pp) and sections 354 and 2128 of the Public Health Service Act (PHS Act) (42 U.S.C. 263b and 300aa–28).

TABLE 1.—CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS

U.S.C. Section	Description of Violation	Current Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
21 U.S.C.					
333(b)(2)(A)	Violation of certain requirements of the Prescription Drug Marketing Act (PDMA)	50,000	For each of the first two violations in any 10-year period	1988	55,000
333(b)(2)(B)	Violation of certain requirements of the PDMA	1,000,000	For each violation after the second conviction in any 10-year period	1988	1,100,000
333(b)(3)	Violation of certain requirements of the PDMA	100,000	Per violation	1988	110,000
333(f)(1)(A)	Violation of certain requirements of the Safe Medical Devices Act (SMDA)	15,000	Per violation	1990	15,000

TABLE 1.—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	Adjusted Maximum Penalty Amount (in dollars)
333(f)(1)(A)	Violation of certain requirements of the SMDA	1,000,000	For the aggregate of violations	1990	1,100,000
333(f)(2)(A)	Violation of certain requirements of the Food Quality Protection Act of 1996 (FQPA)	50,000	Per individual	1996	55,000
333(f)(2)(A)	Violation of certain requirements of the FQPA	250,000	Per ''any other person''	1996	275,000
333(f)(2)(A)	Violation of certain requirements of the FQPA	500,000	For all violations adjudicated in a single proceeding	1996	550,000
335b(a)	Violation of certain requirements of the Generic Drug Enforcement Act of 1992 (GDEA)	250,000	Per violation for an individual	1992	275,000
335b(a)	Violation of certain requirements of the GDEA	1,000,000	Per violation for ''any other person''	1992	1,100,000
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	1968	1,000
360pp(b)(1)	Violation of certain requirements of the RCHSA	300,000	For any related series of violations	1968	325,000
42 U.S.C.					
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	1992	10,000
300aa–28(b)(1)	Violation of certain requirements of the National Childhood Vaccine Injury Act of 1986	100,000	Per occurrence	1986	110,000

In several cases, the adjusted civil monetary penalty was subject to the FCPIAA's provision restricting the initial adjustment to no more than 10 percent of the penalty. In several other cases, the adjusted civil monetary penalty did not change from the current civil monetary penalty.

II. What Would the Proposed Rule Do?

The proposal would amend our civil money penalties hearing regulations in part 17 (21 CFR part 17) to establish a new § 17.2, entitled ''Maximum Penalty Amounts,'' to show the current maximum civil monetary penalty amounts that were adjusted under the FCPIAA. Proposed § 17.2 would be similar to the table shown in section I of this document, except that the proposal would use a yet-to-be-determined date as the ''Date of Last Penalty Figure or Adjustment'' because that date would reflect a final rule's effective date and, at this time, we cannot predict when we would issue a final rule.

We would revise the table in § 17.2, as required by the FCPIAA, at least once every 4 years.

The proposal would also revise § 17.1 which lists, in part, statutory provisions that authorize civil money penalties that are governed by the civil money penalty regulations. The proposed revision would simply update the statutory citations because some provisions have been renumbered since the last time we amended § 17.1.

We also note that section 351(d)(2) of the PHS Act (42 U.S.C. 262(d)(2)) authorizes a civil monetary penalty for certain violations of the PHS Act. We have omitted section 351(d)(2) of the PHS Act from this proposal because, unlike the other civil monetary penalty provisions, section 351(d)(2) of the PHS Act is self-adjusting so that the maximum civil monetary penalty amount increases annually. Section 351(d)(2) of the PHS Act, when first enacted in 1986, provided for a maximum civil penalty of up to $100,000 per day of violation. By using the adjustment formula prescribed in section 351(d)(2) of the PHS Act, we calculate the adjusted maximum civil penalty amount for section 351(d)(2) of the PHS Act to be $151,637.28 per day of violation.

III. Environmental Impact

We have determined under 21 CFR 25.30(a) and (h) 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.

IV. Paperwork Reduction Act 1995

We tentatively conclude that the civil monetary penalties adjustments in this proposed rule are not subject to review

by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The adjustments do not require disclosure of any information to FDA, third parties, or the public.

V. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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). We believe 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. Because the proposed rule would simply adjust the maximum amount of civil monetary penalties administered by FDA, and because the adjustment is required by the FCPIAA, we certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed 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.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 17 be amended as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

1. The authority citation for 21 CFR part 17 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

2. Section 17.1 is amended by revising paragraph (a), redesignating paragraphs (d) through (f) as paragraphs (e) through (g), adding new paragraph (d), and revising newly redesignated paragraphs (e), (f), and (g) to read as follows:

§ 17.1 Scope.

* * * * *

(a) Section 303(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) authorizing civil money penalties for certain violations of the act that relate to prescription drug marketing practices.

* * * * *

(d) Section 539(b)(1) of the act authorizing civil money penalties for certain violations of the act that relate to electronic products.

(e) Section 351(d)(2) of the Public Health Service Act (the PHS Act) authorizing civil money penalties for violations of biologic recall orders.

(f) Section 354(h)(3) of the PHS Act, as amended by the Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Act of 1998, authorizing civil money penalties for failure to obtain a certificate and failure to comply with established standards, among other things.

(g) Section 2128(b)(1) of the PHS Act authorizing civil money penalties for intentionally destroying, altering, falsifying, or concealing any record or report required to be prepared, maintained, or submitted by vaccine manufacturers under section 2128 of the PHS Act.

3. Section 17.2 is added to read as follows:

§ 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

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

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)
(a) 21 U.S.C.					
(1) 333(b)(2)(A)	Violation of certain requirements of the Prescription Drug Marketing Act (PDMA)	50,000	For each of the first two violations in any 10-year period	----	55,000
(2) 333(b)(2)(B)	Violation of certain requirements of the PDMA	1,000,000	For each violation after the second conviction in any 10-year period	----	1,100,000

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]

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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.