

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing 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: This rule is effective on [*insert date 60 days after date of publication in the Federal Register*].

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.

In the **Federal Register** of December 1, 2003 (68 FR 67094), we published a proposed rule that identified 14 civil monetary penalties that fall within our jurisdiction and are subject to adjustments under the FCPIAA. The proposal amended our civil money penalties hearing regulations at 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.

The proposal also revised § 17.1 which lists statutory provisions authorizing civil money penalties that were governed by the civil money penalty regulations as of August 28, 1995. The proposed revision simply updated the statutory citations.

II. What Comments Did We Receive on the Proposal?

We received two comments on the proposed rule. A description of those comments and our responses follow. To make it easier to identify comments and our responses, the word “Comment,” in parentheses, will appear before the comment’s description, and the word “Response,” in parentheses, will appear before our response. We have also numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment’s value or importance or the order in which it was received.

(Comment 1) One comment stated that the adjusted penalties were not severe enough to “keep crooked manufacturers from stopping their criminal acts which injure the American people.” The comment said that the penalties should be increased by another 25 percent, and claimed that some drugs have caused more harm than benefits to individuals.

The comment also made remarks concerning compensation afforded to pharmaceutical executives and the drug approval process.

(Response) As we previously stated and in the preamble to the proposed rule, the FCPIAA prescribes a formula for calculating the increase for a civil monetary penalty and states that the initial adjustment of a civil monetary penalty may not exceed 10 percent of the penalty. (See 68 FR at 67094.) Thus,

while higher civil monetary penalties might be a better deterrent, the FCPIAA does not authorize increases in penalties greater than 10 percent. Instead, the FCPIAA creates a framework for calculating and limiting the increases to a civil monetary penalty, and so the comment’s suggestion to increase the penalties by 25 percent is not consistent with the FCPIAA.

As for the comment’s remarks concerning alleged harm from human drug products, executive compensation, and drug approval, such matters are outside the scope of this rulemaking.

(Comment 2) A comment from the General Accounting Office stated that we had miscalculated the increases for several civil monetary penalties and that the correct amounts should be higher. The comment said that four of the proposed adjustments were not consistent with the law regarding inflation increases and explained that the errors were probably due to applying the specified 10-percent cap before rounding instead of after the prescribed rounding. Thus, because all 14 rounded CPI adjustments exceeded the specified 10-percent cap, each penalty should be increased by exactly 10 percent to be consistent with the FCPIAA.

Consequently, the four civil monetary penalty adjustments, as originally proposed and as revised under the comment’s interpretation of the FCPIAA’s rounding and increase cap formulas, are as follows:

TABLE 1.—FOUR CIVIL MONETARY PENALTIES AS ADJUSTED BY FDA IN THE PROPOSED RULE AND READJUSTED UNDER COMMENT 2 OF SECTION II OF THIS DOCUMENT

U.S. Code Citation	Description of Violation	Current Maximum Penalty Amount (in dollars)	Adjusted Penalty, as Proposed by FDA	Adjusted Penalty, as Recalculated
21 U.S.C.				
333(f)(1)(A)	Violation of certain requirements of the Safe Medical Devices Act	15,000	15,000	16,500
360pp(b)(1)	Violation of certain requirements of the Radiation Control for Health and Safety Act of 1968 (RCHSA)	1,000	1,000	1,100
360pp(b)(1)	Violation of certain requirements of the RCHSA	300,000	325,000	330,000
42 U.S.C.				

TABLE 1.—FOUR CIVIL MONETARY PENALTIES AS ADJUSTED BY FDA IN THE PROPOSED RULE AND READJUSTED UNDER COMMENT 2 OF SECTION II OF THIS DOCUMENT—Continued

U.S. Code Citation	Description of Violation	Current Maximum Penalty Amount (in dollars)	Adjusted Penalty, as Proposed by FDA	Adjusted Penalty, as Recalculated
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	10,000	11,000

(Response) We agree with the comment and have revised § 17.2 accordingly.

We also note that proposed § 17.2 contained a table to show the civil monetary penalties, including:

- “Description of Violation” to explain what actions could lead to a civil monetary penalty;
- “Current Maximum Penalty Amount (in dollars)”;
- “Assessment Method” to explain how each civil monetary penalty might be applied;
- “Date of Last Penalty Figure or Adjustment” because, under the FCPIAA, we are obligated to adjust the maximum penalty amounts periodically; and
- “Adjusted Maximum Penalty Amount (in dollars)”.

The column for the “Date of Last Penalty Figure or Adjustment” was left blank because we did not know when we might issue a final rule. Because we are now issuing this final rule, the “Date of Last Penalty Figure or Adjustment” in each column will now be “2004.”

We have also revised the column that originally read as “Current Maximum Penalty Amount (in dollars)” to read as “Former Maximum Penalty Amount (in dollars).” We replaced “Current” with “Former” to eliminate any potential confusion about whether the “Current Maximum Penalty” should apply or whether the “Adjusted Maximum Penalty” should apply.

III. What Other Changes Did We Make?

Proposed § 17.1 revised the list of statutory civil monetary penalties. In revising the list, we inadvertently omitted two revisions to § 17.1(b), which refers to section 303(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 333(g)) and civil money penalties for certain violations of the act that relate to medical devices. The first omission would correct the citation so that it referred to section 303(f)(1)(A) of the act. We accounted for the correct citation in proposed § 17.2(a), but neglected to propose a corresponding citation change in proposed § 17.1(b). The second omission was a reference to section 303(f)(2) of the act, which provides for monetary penalties for certain violations related to pesticide residues. We included a reference to 21 U.S.C. 333(f)(2) in proposed § 17.2, but neglected to make a corresponding change to § 17.1(b).

Consequently, on our own initiative, we have revised § 17.1(b) to delete the reference to section 303(g) of the act and to insert references to section 303(f)(1) and (f)(2) of the act.

Additionally, the introductory text of § 17.1 contains a sentence that reads, in relevant part, “Listed below are the statutory provisions that as of August 28, 1995, authorize civil money penalties that are governed by these procedures.” Because we have updated the citations to reflect current laws, the August 28, 1995, date is no longer appropriate. Therefore, this final rule deletes “August 28, 1995” and revises the sentence to read as follows: “Listed below are the statutory provisions that authorize civil money penalties that are governed by these procedures.”

IV. What Does the Final Rule Do?

In brief, the final rule:

- Revises § 17.1 to update the statutory citations regarding various civil monetary penalties and
- Creates a new § 17.2, entitled “Maximum penalty amounts,” to show the maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the act or the Public Health Service Act (PHS Act).

We remind readers 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 omitted section 351(d)(2) of the PHS Act from this rule 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.

V. 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.

VI. Paperwork Reduction Act 1995

We conclude that the civil monetary penalties adjustments in this final 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.

VII. Federalism

We have analyzed this final 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.

VIII. Analysis of Impacts

We have examined the impacts of the final 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). This final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final 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 final rule simply adjusts the maximum amount of civil monetary penalties administered by FDA, and because the adjustment is required by the FCPIAA, we certify that the final 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.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

■ Therefore, under the Federal Food, Drug, and Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 17 is 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 redesignating paragraphs (e) through (g); by revising the introductory text, paragraphs (a), (b), and newly redesignated paragraphs (e) through (g); and by adding new paragraph (d) to read as follows:

§ 17.1 Scope.

This part sets forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA. Listed below are the statutory provisions that authorize civil money penalties that are governed by these procedures.

(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.

(b) Section 303(f)(1) of the act authorizing civil money penalties for certain violations of the act that relate to medical devices and section 303(f)(2) of the

act authorizing civil money penalties for certain violations of the act that relate to pesticide residues.

* * * * *

(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 act or the Public Service Act.

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

U.S.C. Section	Description of Violation	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty	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	2004	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	2004	1,100,000
(3) 333(b)(3)	Violation of certain requirements of the PDMA	100,000	Per violation	2004	110,000
(4) 333(f)(1)(A)	Violation of certain requirements of the Safe Medical Devices Act (SMDA)	15,000	Per violation	2004	16,000

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

U.S.C. Section	Description of Violation	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty	Adjusted Maximum Penalty Amount (in dollars)
(5) 333(f)(1)(A)	Violation of certain requirements of the SMDA	1,000,000	For the aggregate of violations	2004	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	2004	55,000
(7) 333(f)(2)(A)	Violation of certain requirements of the FQPA	250,000	Per "any other person"	2004	275,000
(8) 333(f)(2)(A)	Violation of certain requirements of the FQPA	500,000	For all violations adjudicated in a single proceeding	2004	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	2004	275,000
(10) 335b(a)	Violation of certain requirements of the GDEA	1,000,000	Per violation for "any other person"	2004	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	2004	1,000
(12) 360pp(b)(1)	Violation of certain requirements of the RCHSA	300,000	For any related series of violations	2004	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	2004	11,000
(2) 300aa-28(b)(1)	Violation of certain requirements of the National Childhood Vaccine Injury Act of 1986	100,000	Per occurrence	2004	110,000

Dated: July 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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

BILLING CODE 4160-01-S