

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