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United States General Accounting Office
Washington, DC 20548

August 1, 2002

The Honorable Tommy Thompson
Secretary
Department of Health and Human Services

Subject: *Food and Drug Administration's Compliance With the Inflation
Adjustment Act*

Dear Secretary Thompson:

Earlier this year, we initiated a governmentwide review of the implementation of the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended (Inflation Adjustment Act).¹ The Inflation Adjustment Act required each federal agency to issue a regulation adjusting its covered maximum civil monetary penalties for inflation by October 23, 1996, and requires them to make necessary adjustments at least once every 4 years thereafter. During our review, the Food and Drug Administration's (FDA) Office of the Chief Counsel indicated that at least 14 of the agency's civil penalties are covered by the act but the agency had not adjusted any of them for inflation. This report is intended to bring this matter to your attention and to recommend corrective action.

FDA Identified At Least 14 Civil Penalties That Are Covered by the Inflation Adjustment Act

Section 3 of the Inflation Adjustment Act defines a covered civil penalty as any "penalty, fine, or other sanction that ... is for a specific monetary amount as provided by Federal law" or "has a maximum amount provided for by Federal law," and "is assessed or enforced by an agency pursuant to Federal law" and "is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts." FDA's Office of the Chief Counsel provided us with a list of civil penalties that it considered covered by the Inflation Adjustment Act. Table 1 lists those penalties as well as their maximum penalty amounts, assessment methods, and the dates that the penalties were last set or adjusted.

¹The Inflation Adjustment Act is codified at 28 U.S.C. 2461 note. The 1990 act was amended in 1996 by the Debt Collection Improvement Act, which added the requirement for agencies to adjust their civil penalties by regulation (Pub. Law 104-134, Sec. 31001, 110 Stat. 1321-373).

Table 1: FDA Civil Penalties Covered by the Inflation Adjustment Act

U.S.C. citation	Description of violation	Maximum penalty amount	Assessment method	Date penalty was last set or adjusted
21 U.S.C. 333(b)(2)(A)	Violation of certain requirements of the Prescription Drug Marketing Act of 1988	\$50,000	For each of the first two violations in any 10-year period	1988
21 U.S.C. 333(b)(2)(B)	Violation of certain requirements of the Prescription Drug Marketing Act of 1988	\$1,000,000	For each violation after the second conviction in any 10-year period	1988
21 U.S.C. 333(b)(3)	Violation of certain requirements of the Prescription Drug Marketing Act of 1988	\$100,000	Per violation	1988
21 U.S.C. 333(f)(1)(A)	Violation of certain requirements of the Safe Medical Devices Act of 1990	\$15,000	Per violation	1990
21 U.S.C. 333(f)(1)(A)	Violation of certain requirements of the Safe Medical Devices Act of 1990	\$1,000,000	For the aggregate of violations	1990
21 U.S.C. 333(f)(2)(A)	Violation of certain requirements of the Food Quality Protection Act of 1996	\$50,000	Per individual	1996
21 U.S.C. 333(f)(2)(A)	Violation of certain requirements of the Food Quality Protection Act of 1996	\$250,000	Per "any other person"	1996
21 U.S.C. 333(f)(2)(A)	Violation of certain requirements of the Food Quality Protection Act of 1996	\$500,000	For all violations adjudicated in a single proceeding	1996
21 U.S.C. 335b(a)(7)	Violation of certain requirements of the Generic Drug Enforcement Act of 1992	\$250,000	Per violation for an individual	1992
21 U.S.C. 335b(a)(7)	Violation of certain requirements of the Generic Drug Enforcement Act of 1992	\$1,000,000	Per violation for "any other person"	1992

21 U.S.C. 360pp(b)(1)	Violation of certain requirements of the Radiation Control for Health and Safety Act of 1968	\$1,000	Per violation per person	1968
21 U.S.C. 360pp(b)(1)	Violation of certain requirements of the Radiation Control for Health and Safety Act of 1968	\$300,000	For any related series of violations	1968
42 U.S.C. 263b (h)(3)	Violation of certain requirements of the Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Reauthorization Act of 1998	\$10,000	Per violation	1992
42 U.S.C. 300aa-28(b)	Violation of certain requirements of the National Childhood Vaccine Injury Act of 1986	\$100,000	Per occurrence	1986

Note: For purposes of this report, we considered different penalty amounts within the same statutory provision (e.g., per violations and for the aggregate of violations) to be separate civil penalties.

Source: FDA's Office of Chief Counsel.

FDA Has Not Adjusted Its Covered Civil Penalties for Inflation

Under the Inflation Adjustment Act, FDA (like other covered federal agencies) was required to publish a regulation by October 23, 1996, adjusting its maximum civil penalties for inflation. The amount of the adjustment was to be based on changes in the Consumer Price Index (CPI) between June of the calendar year in which the penalty was last set or adjusted and June of the year prior to the adjustment (i.e., June 1995 for adjustments made in October 1996). However, the statute limited the first adjustments of the agencies' penalties to 10 percent of the penalty amounts. Because the CPI had increased by more than 10 percent since 8 of the 14 civil penalties in table 1 were last set or adjusted, FDA should have published a regulation in the *Federal Register* by October 23, 1996, increasing each of these 8 penalties by 10 percent. Three of the 14 penalties were last set or adjusted in 1992, and the CPI increased by nearly 9 percent between June 1992 and June 1995. Therefore, FDA could have increased these penalties as well. The remaining three penalties were last set or adjusted in 1996, so FDA could not have increased them in October 1996.

The Inflation Adjustment Act also required FDA to examine its civil penalties by October 23, 2000, and, if necessary, to make a second round of inflation adjustments. The calendar year 2000 adjustments were to be based on changes in the CPI between

June of the year in which the penalties were last adjusted (e.g., June 1996) and June of the year prior to the adjustment (June 1999). If FDA had adjusted its civil penalties in 1996, the agency could have increased its penalty amounts again in 2000.

However, our review of the *Federal Register* for calendar years 1996 through 2001 did not reveal any FDA regulations that increased the agency's civil penalties for inflation. One of FDA's Associate Chief Counsels confirmed that FDA had not published any penalty adjustment regulations pursuant to the Inflation Adjustment Act, but was not aware why the agency had not done so.

Recommendation for Executive Action

We recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to initiate a regulatory action to adjust for inflation all of the agency's civil penalties that are covered by the Inflation Adjustment Act.

Agency Comments and Our Evaluation

On July 17, 2002, we provided a draft of this report to the Secretary of the Department of Health and Human Services for his review and comment. On July 30, 2002, the Department indicated that the FDA Deputy Commissioner was directing his staff to prepare a draft regulation that would adjust the agency's civil penalties by 10 percent—the maximum allowed by the statute for a first-time adjustment. The Department also said that the draft regulation would provide for periodic adjustments thereafter as required by law.

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We are sending copies of this report to the appropriate congressional committees, and it will be available on GAO's homepage at <http://www.gao.gov>. If you or your staff have any questions on the matters discussed in this letter, you may contact Curtis Copeland or me at (202) 512-6806. Major contributors to this report include John Tavares and Oliver Walker.

Sincerely yours,



Victor S. Rezendes
Managing Director
Strategic Issues

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