

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