

**§ 17.2**

**21 CFR Ch. I (4–1–08 Edition)**

(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.

(c) Section 307 of the act authorizing civil money penalties for certain actions in connection with an abbreviated new drug application or certain actions in connection with a person or individual debarred under section 306 of the act.

(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.

[60 FR 38626, July 27, 1995, as amended at 69 FR 43301, July 20, 2004]

**§ 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 Health 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                 | 16,500                                       |
| (5) 333(f)(1)(A) | Violation of certain requirements of the SMDA                                   | 1,000,000                                  | For the aggregate of violations                                      | 2004                 | 1,100,000                                    |

**Food and Drug Administration, HHS**

**§ 17.3**

**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) |
|--------------------|--|--|---|----------------------|--|
| (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                 | 1,100  |
| (12) 360pp(b)(1)   | Violation of certain requirements of the RCHSA   | 300,000                                    | For any related series of violations                  | 2004                 | 330,000                                      |
| (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                                      |

[69 FR 43301, July 20, 2004; 69 FR 49807, Aug. 12, 2004, as amended at 73 FR 15884, Mar. 26, 2008]

**§ 17.3 Definitions.**

The following definitions are applicable in this part:

(a) For specific acts giving rise to civil money penalty actions brought under 21 U.S.C. 333(g)(1):

(1) *Significant departure*, for the purpose of interpreting 21 U.S.C.

333(g)(1)(B)(i), means a departure from requirements that is either a single major incident or a series of incidents that collectively are consequential.

(2) *Knowing departure*, for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(i), means a departure from a requirement taken: (a) With actual