

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. 2003N-0308]

DDM

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Certifier A. Corbin

**Civil Money Penalties Hearings; Maximum Penalty Amounts and Compliance  
With the Federal Civil Penalties Inflation Adjustment Act; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; correction.

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**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that published in the **Federal Register** of July 20, 2004 (69 FR 43299). The document issued a regulation to adjust for inflation the maximum civil money penalty amounts for various civil money penalty authorities within our jurisdiction. The document published with some errors and this document corrects those errors.

**DATES:** The rule is effective September 20, 2004.

**FOR FURTHER INFORMATION CONTACT:** Joyce A. Strong, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville MD, 20857, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 04-16388, appearing on page 43299 in the **Federal Register** of Tuesday, July 20, 2004, the following corrections are made:

**§ 17.2 [Corrected]**

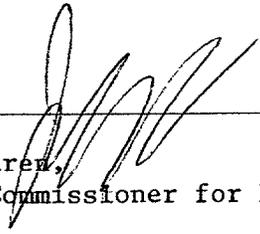
1. On pages 43301 and 43302, in the last column of the table (in dollars), paragraphs (a)(4), (a)(11), and (a)(12) are corrected to read: 16,500, 1,100, and

330,000, respectively. For the convenience of the reader, the table is republished in its entirety:

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
(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

Dated: 8/5/04  
August 5, 2004.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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

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