

by the Office of Management and Budget because they do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The adjustments do not require disclosure of any information to FDA, third parties, or the public.

V. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would simply adjust the maximum amount of civil monetary penalties administered by FDA, and because the adjustment is required by the FCPIAA, we certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.
Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 17 be amended as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

- 1. The authority citation for 21 CFR part 17 continues to read as follows:
Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

2. Section 17.1 is amended by revising paragraph (a), redesignating paragraphs (d) through (f) as paragraphs (e) through (g), adding new paragraph (d), and revising newly redesignated paragraphs (e), (f), and (g) to read as follows:

§ 17.1 Scope.

(a) Section 303(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) authorizing civil money penalties for certain violations of the act that relate to prescription drug marketing practices.

(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.

3. Section 17.2 is added to read as follows:

§ 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the Federal Food, Drug, and Cosmetic 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	Current Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment ¹	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	----	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	----	1,100,000