Division of Financial Management and then deposited in the U.S. Treasury.

32. In addition, the following revisions have been made to other regulations:

a. Section 5.99, regarding issuance of notices and orders relating to civil money penalties, has been deleted (see the Background section of this document).

b. Section 10.50(c)(21), regarding opportunities for a hearing under 21 CFR part 12, has been deleted (paragraph 9).

c. Section 20.86, regarding disclosure of data and information in administrative proceedings, has been revised to include part 17 (paragraph 81).

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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. The final rule specifies the procedures to be followed by persons who have the right to a hearing on the administrative imposition of civil money penalties by the agency. As such, the rule does not impose any burden on regulated industry. Because the procedures themselves are protections and do not impose significant costs beyond what the underlying statute imposes, the agency certifies that the final 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.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 17

Administrative practice and procedure, Animal drugs, Biologics, Civil money penalties hearings, Drugs, Generic drugs, Prescription drugs samples, Medical devices.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

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, Title 21, Chapter 1 of the Code of Federal Regulations is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354, 361, 362, 1701–1706, 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b, 264, 265, 300u–300u–5, 300aa–1, 300aa–25, 300aa–27, 300aa–28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99–660 (42 U.S.C. 300aa–1 note).

§ 5.99 [Removed]

2. Section 5.99 *Issuance of notices and orders relating to the administrative imposition of civil money penalties under various statutes* is removed.

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

3. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 354, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. 551–558, 701–721; 28 U.S.C. 2112.

§ 10.50 [Amended]

4. Section 10.50 *Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing* is amended by removing paragraph (c)(21).

5. New part 17 is added to read as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

Sec.

Authority: Secs. 301, 303, 307, 501, 502, 505, 510, 513, 516, 519, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371); sec. 351, 354, 2128 of the Public Health Service Act (42 U.S.C. 262, 263b, 300aa-28); 5 U.S.C. 554, 555, 556, 557.

§ 17.1 Scope.

This part sets forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA. Listed below are the statutory provisions that as of August 28, 1995, authorize civil money