



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. FDA-2017-N-0011]

Civil Money Penalty Definitions; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending a civil money penalty regulation to correct a statutory reference to align the regulations with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and to ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4248, Silver Spring, MD 20993-0002, 301-796-4830.

SUPPLEMENTARY INFORMATION: FDA is amending its regulation at 21 CFR 17.3 to correct a statutory reference to reflect the current citation. FDA is revising § 17.3(a)(1) through (4) by replacing section "333(g)" with section "333(f)." On July 27, 1995, FDA published a final rule establishing hearing procedures for use when FDA proposes the imposition of administrative civil money penalties (60 FR 38612 at 38626). The document was published with a citation to 21 U.S.C. 333(g) (303(g) of the FD&C Act) that subsequently was changed to 21

U.S.C. 333(f) (303(f) of the FD&C Act) by section 226(b)(1) of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85).

Publication of this document constitutes final action on the change under the Administrative Procedure Act (5 U.S.C. 553). This technical amendment is nonsubstantive and merely updates and corrects a statutory reference in the Code of Federal Regulations (CFR) that is no longer current. FDA therefore, for good cause, has determined that notice and public comment are unnecessary under 5 U.S.C. 553(b)(3)(B). Further, this rule places no burden on affected parties for which such parties would need a reasonable time to prepare for the effective date of the rule. Accordingly, FDA, for good cause, has determined this technical amendment to be exempt under 5 U.S.C. 553(d)(3) and that the rule can become effective upon publication.

FDA has determined under 21 CFR 25.30(i) that this final rule 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. In addition, FDA has determined that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-20) is not required.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 17 is amended as follows:

#### **PART 17--CIVIL MONEY PENALTIES HEARINGS**

1. The authority citation for 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. In § 17.3, paragraph (a) is revised to read as follows:

§ 17.3 Definitions.

\* \* \* \* \*

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

(1) Significant departure, for the purpose of interpreting 21 U.S.C. 333(f)(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(f)(1)(B)(i), means a departure from a requirement taken:

- (i) With actual knowledge that the action is such a departure; or
- (ii) In deliberate ignorance of a requirement; or
- (ii) In reckless disregard of a requirement.

(3) Minor violations, for the purposes of interpreting 21 U.S.C. 333(f)(1)(B)(ii), means departures from requirements that do not rise to a level of a single major incident or a series of incidents that are collectively consequential.

(4) Defective, for the purposes of interpreting 21 U.S.C. 333(f)(1)(B)(iii), includes any defect in performance, manufacture, construction, components, materials, specifications, design, installation, maintenance, or service of a device, or any defect in mechanical, physical, or chemical properties of a device.

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Dated: July 18, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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