



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. FDA-2014-N-01113]

Maximum Civil Money Penalty Amounts; Civil Money Penalty Complaints; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of June 18, 2014, for the direct final rule that appeared in the Federal Register of February 3, 2014. The direct final rule revises the regulations to update the table to adjust the preceding maximum civil penalty amounts for inflation as prescribed by the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA). The direct final rule also revises the regulations to amend the process for initiating certain civil money penalty (CMP) administrative actions. This document confirms the effective date of the direct final rule.

DATES: Effective date of the direct final rule published in the Federal Register of February 3, 2014 (79 FR 6088), confirmed: June 18, 2014.

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301-796-4830.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 3, 2014 (79 FR 6088), FDA published the direct final rule Maximum Civil Money Penalty Amounts; Civil Money Penalty Complaints. The direct final rule revises the table in 21 CFR 17.2 to adjust the

preceding maximum CMP amounts for inflation as prescribed by FCPIAA. The adjusted CMPs have been updated to account for the inflation as prescribed by FCPIAA. The direct final rule also revises 21 CFR 17.5(a) to provide authority for the Chief Counsel to delegate the responsibility for initiating a CMP administrative action against a tobacco retailer.

FDA also solicited comments concerning the changes for a 75-day period ending April 21, 2014, in a proposed rule that published in the Federal Register of February 3, 2014 (79 FR 6112). FDA stated that the effective date of the direct final rule would be June 18, 2014, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: 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, 21 CFR part 17 is amended. Accordingly, the amendments issued thereby are effective.

Dated: June 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.