4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. FDA-2014-N-0113]

Maximum Civil Money Penalty Amounts; Civil Money Penalty Complaints

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a new regulation to adjust for inflation the maximum civil money penalty (CMP) amounts for the various CMP authorities within our jurisdiction and to amend the process for initiating certain CMP administrative actions. We are taking these actions to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), as amended, and to streamline our internal processes. The last CMP adjustment was published in the Federal Register of November 12, 2008, and the FCPIAA requires Federal Agencies to adjust their CMPs at least once every 4 years. We are using direct final rulemaking for these actions because the Agency expects that there will be no significant adverse comment on the rule. We are concurrently proposing and soliciting comments on this rule. If significant adverse comments are received, we will withdraw this final rule and address the comments in a subsequent final rule. FDA will not provide additional opportunity for comment.

DATES: This rule is effective [INSERT DATE 135 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], without further notice, unless FDA receives significant adverse comment by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE

FEDERAL REGISTER]. If we receive no timely significant adverse comments, we will publish a document in the Federal Register before [INSERT DATE 105 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], confirming the effective date of the direct final rule. If we receive any timely significant adverse comments, we will publish a document in the Federal Register withdrawing this direct final rule before [INSERT DATE 135 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. FDA-2014-N-0113, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2014-N-0113 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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: The last CMP adjustment was published in the Federal Register of November 12, 2008 (73 FR 66750).

I. Background

A. CMP Amounts

FDA is amending § 17.2 (21 CFR 17.2) to update the maximum CMP amounts. In general, FCPIAA requires Federal Agencies to issue regulations to adjust for inflation each CMP penalty provided by law within their jurisdiction. (28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3701)). FCPIAA directs Agencies to adjust the CMP provided by law by October 23, 1996, and to make additional adjustments at least once every 4 years thereafter. The adjustments are based on changes in the cost of living, and the FCPIAA defines the cost of living adjustment as the percentage (if any) for each civil monetary penalty by which the Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law (28 U.S.C. 2461 note, section 5(b)).

FCPIAA also prescribes a rounding method based on the size of the penalty after the calculated increase, but states that the adjustment of a CMP may not exceed 10 percent of the

penalty. FCPIAA defines a CMP as any penalty, fine, or other sanction that is for a specific monetary amount as provided by Federal law; or has a maximum amount provided for by Federal law; and is assessed or enforced by an agency pursuant to Federal law; and is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal Courts (28 U.S.C. 2461 note, section 3(2)).

B. CMP Complaints

Currently, under § 17.5(a) (21 CFR 17.5(a)), CMP complaints against retailers of tobacco products may only be signed by attorneys in FDA's Office of the Chief Counsel (OCC). Given the routine nature of many of these CMPs, FDA is amending this regulation to permit the Chief Counsel to designate other FDA staff, such as those in FDA's Center for Tobacco Products, to sign a tobacco retailer CMP complaint.

Based on FDA's experience, the large majority of the tobacco retailer complaints to date have involved alleged violations of the requirement to not sell cigarettes and smokeless tobacco to any person younger than 18 years of age or to verify age in accordance with 21 CFR 1140.14(b). These complaints have almost always been straightforward, they involve simple fact patterns, and they do not require a complex legal analysis. Over time, such CMP complaints have increased in volume, and we anticipate that the volume will continue to be relatively high.

We have determined that, with certain limitations and controls, non-attorney staff outside OCC can carry out the function of reviewing the evidence and signing the tobacco retailer CMP complaints in appropriate circumstances. The proposed amendment to § 17.5(a) would give this decisionmaking authority to the Chief Counsel, who could ensure the authority to sign complaints is only given to appropriate staff and under appropriate circumstances. Under the

proposal, the Chief Counsel would have the authority to set and revise limitations and controls, and to broaden, limit, or rescind any authorizations to sign tobacco retailer CMP complaints.

The limitations could include, for example, limiting the delegation to situations where the CMP amount is below a certain dollar value; the CMP involves specified tobacco retailer charges that OCC has determined are routine and predictable and do not require a complex legal analysis; and involve charges for which FDA has developed OCC-approved templates, parameters, and procedures. The controls could include, for example, an audit or other quality review.

FDA is publishing this rule as a direct final rule without prior proposal and comment because we view these as noncontroversial amendments and anticipate no significant adverse comment. This rule incorporates requirements specifically set forth in the FCPIAA requiring FDA to issue a regulation implementing inflation adjustments for all its CMP provisions. These technical changes, required by law, do not substantively alter the existing regulatory framework, nor do they in any way affect the terms under which CMPs are assessed by FDA. The formula for the amount of the penalty adjustment is prescribed by Congress in the FCPIAA, and these changes are not subject to the exercise of discretion by FDA. The amendment to § 17.5(a) changes an internal process.

This direct final rule:

- Revises the table in § 17.2 to adjust the maximum CMP amounts for inflation as prescribed by FCPIAA.
- Revises § 17.5(a) to provide authority for the Chief Counsel to delegate the responsibility for initiating a CMP administrative action against a tobacco retailer.

II. Environmental Impact

The Agency has determined under 21 CFR 25.33 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.

III. Paperwork Reduction Act

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has 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, the Agency has 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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct 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 not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that

would minimize any significant impact of a rule on small entities. Because the final rule simply adjusts the maximum amount of CMPs administered by FDA as required by the FCPIAA, and because the proposed rule makes a change to FDA's internal processes, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at http://www.regulations.gov.

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, 21 CFR part 17 is 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 17.2 is revised 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	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
21 U.S.C.				
333(b)(2)(A)	60,000	For each of the first two violations in any 10-year period	2013	65,000
333(b)(2)(B)	1,200,000	For each violation after the second conviction in any 10-year period	2013	1,275,000
333(b)(3)	120,000	Per violation	2013	130,000
333(f)(1)(A)	16,500	Per violation	2008	16,500 (not adjusted)
333(f)(1)(A)	1,200,000	For the aggregate of violations	2013	1,275,000
333(f)(2)(A)	55,000	Per individual	2013	60,000
333(f)(2)(A)	300,000	Per "any other person"	2013	325,000
333(f)(2)(A)	600,000	For all violations	2013	650,000

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
		adjudicated in a single proceeding		
333(f)(3)(A)	10,000	For all violations adjudicated in a single proceeding	2013	11,000
333(f)(3)(B)	10,000	For each day the violation is not corrected after a 30-day period following notification until the violation is corrected	2013	11,000
333(f)(4)(A)(i)	250,000	Per violation	2013	275,000
333(f)(4)(A)(i)	1,000,000	For all violations adjudicated in a single proceeding	2013	1,075,000
333(f)(4)(A)(ii)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification	2013	275,000
333(f)(4)(A)(ii)	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day violation	2013	1,075,000
333(f)(4)(A)(ii)	10,000,000	For all violations adjudicated in a single proceeding	2013	10,850,000
333(f)(9)(A)	15,000	Per violation	2009	15,000 (not adjusted)
333(f)(9)(A)	1,000,000	For all violations adjudicated in a single proceeding	2013	1,050,000
333(f)(9)(B)(i)(I)	250,000	Per violation	2013	275,000
333(f)(9)(B)(i)(I)	1,000,000	For all violations adjudicated in a single proceeding	2013	1,050,000
333(f)(9)(B)(i)(II)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification	2013	275,000
333(f)(9)(B)(i)(II)	1,000,000	For any 30-day period, where the amount doubles	2013	1,050,000

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
		for every 30-day period of continued violation after the first 30-day violation		
333(f)(9)(B)(i)(II)	10,000,000	For all violations adjudicated in a single proceeding	2013	10,525,000
333(f)(9)(B)(ii)(I)	250,000	Per violation	2013	275,000
333(f)(9)(B)(ii)(I)	1,000,000	For all violations adjudicated in a single proceeding	2013	1,050,000
333(f)(9)(B)(ii)(II)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification	2013	275,000
333(f)(9)(B)(ii)(II)	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day violation	2013	1,050,000
333(f)(9)(B)(ii)(II)	10,000,000	For all violations adjudicated in a single proceeding	2013	10,525,000
333(g)(1)	250,000	For the first violation in any 3-year period	2013	275,000
333(g)(1)	500,000	For each subsequent violation in any 3-year period	2013	550,000
333 note	250	For the second violation (following a first violation with a warning) within a 12-month period by a retailer with an approved training program	2009	250 (not adjusted)
333 note	500	For the third violation within a 24-month period by a retailer with an approved training program	2009	500 (not adjusted)
333 note	2,000	For the fourth violation within a 24-month period by a retailer with an approved training program	2009	2,000 (not adjusted)

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
333 note	5,000	For the fifth violation within a 36-month period by a retailer with an approved training program	2009	5,000 (not adjusted)
333 note	10,000	For the sixth or subsequent violation within a 48-month period by a retailer with an approved training program	2013	11,000
333 note	250	For the first violation by a retailer without an approved training program	2009	250 (not adjusted)
333 note	500	For the second violation within a 12-month period by a retailer without an approved training program	2009	500 (not adjusted)
333 note	1,000	For the third violation within a 24-month period by a retailer without an approved training program	2013	1,100
333 note	2,000	For the fourth violation within a 24-month period by a retailer without an approved training program	2009	2,000 (not adjusted)
333 note	5,000	For the fifth violation within a 36-month period by a retailer without an approved training program	2009	5,000 (not adjusted)
333 note	10,000	For the sixth or subsequent violation within a 48-month period by a retailer without an approved training program	2013	11,000
335b(a)	300,000	Per violation for an individual	2013	325,000
335b(a)	1,200,000	Per violation for "any other person"	2013	1,275,000
360pp(b)(1)	1,100	Per violation per person	2008	1,100 (not adjusted)
360pp(b)(1)	355,000	For any related series of violations	2013	375,000

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
42 U.S.C.				
263b(h)(3)	11,000	Per violation	2008	11,000 (not adjusted)
300aa-28(b)(1)	120,000	Per occurrence	2013	130,000

3. In § 17.5, revise paragraph (a) to read as follows:

§ 17.5 Complaint.

(a) The Center with principal jurisdiction over the matter involved shall begin all administrative civil money penalty actions by serving on the respondent(s) a complaint signed by the Office of the Chief Counsel attorney for the Center and by filing a copy of the complaint with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For a civil money penalty action against retailers of tobacco products, the complaint may be signed by any Agency employee designated by the Chief Counsel.

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Dated: January 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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