Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 185

RIN 3206-AN39

Program Fraud Civil Remedies: Civil Monetary Penalty Inflation Adjustment

AGENCY: Office of Personnel Management (OPM). **ACTION:** Interim rule.

SUMMARY: This rule adjusts the level of civil monetary penalties contained in U.S. Office of Personnel Management regulations implementing the Program Fraud Civil Remedies Act of 1986, with

an initial "catch-up" adjustment under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget guidance.

DATES: *Effective Date:* August 1, 2016. *Comment Date:* Comments due on or before August 18, 2016.

ADDRESSES: You may submit comments, identified by RIN 3206–AN39, by any of the following methods:

1. Internet—Send comments via email to *katherine.pickar@opm.gov.*

2. Fax—(202) 606–0082.

3. Mail—Office of the General Counsel, ATTN: Katherine Pickar, Office of Personnel Management, 1900 E St. NW., Washington, DC 20415.

Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to RIN 3206–AN39.

Caution: You should be careful to include in your comments only information that you wish to make publicly available as comments are posted without change, with any personal information provided. OPM strongly urges you not to include in your comments any personal information, such as Social Security numbers, Civil Service Annuity/Final numbers, and/or medical information.

FOR FURTHER INFORMATION CONTACT:

Katherine M. Pickar, Office of the General Counsel, Office of Personnel Management, 1900 E St. NW., Washington, DC 20415, *Katherine.pickar@opm.gov,* (202) 606– 1700.

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) ("the Act"). The Act requires agencies to: (1) Adjust the level of civil monetary penalties with an initial "catch-up" adjustment through an interim final rulemaking, and (2) make subsequent annual adjustments for inflation. The purpose of these adjustments is to maintain the deterrent effect of civil penalties.

This rule adjusts the following civil monetary penalties:

CFR Citation	Description of the penalty	Current penalty	Catchup adjustment	Adjusted penalty
5 CFR 185.103(a)	Civil Penalty for False Claims	\$5,000	\$5,781	\$10,781
5 CFR 185.103(f)(2)	Civil Penalty for False Statements	5,000	5,781	10,781

This interim final rule is being issued without prior public notice or opportunity for public comments. The 2015 Act's amendments to the Inflation Adjustment Act require the agency to adjust penalties initially through an interim final rulemaking, which does not require the agency to complete a notice and comment process prior to promulgating the interim final rule. The amendments also explicitly require the agency to make subsequent annual adjustments notwithstanding 5 U.S.C. 553 (the section of the Administrative Procedure Act that normally requires agencies to engage in notice and comment). Additionally, the formula used for adjusting the amount of civil penalties is given by statute, with no discretion provided to OPM regarding the substance of the adjustments. OPM is charged only with performing ministerial computations to determine the amount of adjustment to the civil

penalties due to increases in the Consumer Price Index for all Urban Consumers (CPI–U).

II. Calculation of Adjustment

The Office of Management and Budget (OMB) issued guidance on calculating the catch-up adjustment. See February 24, 2016, Memorandum for the Heads of Executive Departments and Agencies, from Shaun Donovan, Director, Office of Management and Budget, re: Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. Under this guidance, OPM has identified applicable civil monetary penalties and calculated the catch-up adjustment. A civil monetary penalty is any assessment with a dollar amount that is levied for a violation of a Federal civil statute or regulation, and is assessed or enforceable through a civil action in Federal court or an administrative

proceeding. A civil monetary penalty does not include a penalty levied for violation of a criminal statute, or fees for services, licenses, permits, or other regulatory review. The calculated catchup adjustment is based on the percent change between the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October in the year of the previous adjustment (or in the year of establishment, if no adjustment has been made) and the October 2015 CPI– U.

For purposes of the initial adjustment under the 2015 Act, while 5 CFR part 185 was not promulgated until 1995, the civil penalties listed in part 185 were established in 1986 with the enactment of the Program Fraud Civil Remedies Act of 1986, Public Law 99–509, §§ 6101–6104, 100 Stat. 1874 (October 21, 1986), codified at 31 U.S.C. 3801– 3812. The amount of the penalties have not been changed since 1986. The 1986 establishment of the Program Fraud Civil Remedies Act of 1986 serves as the base figure for the inflation calculation. Between October 1986 and October 2015, the CPI-U has increased by 215.628 percent. The post-adjustment penalty amount or range is obtained by multiplying the pre-adjustment penalty amount or range by the percent change in the CPI-U over the relevant time period, and rounding to the nearest dollar. Therefore, the new, postadjustment penalty under the PFCRA is $5,000 \times 2.15628 = 10,781.40$, which rounds to \$10,781. The new, postadjustment penalties are less than 250 percent of the pre-adjustment penalties, so the limitation on the amount of the adjustment is not implicated.

III. Procedural Requirements

A. Regulatory Impact Analysis: Executive Order 12866, as Supplemented by Executive Order 13563

OPM, with the concurrence of the Office of Management and Budget (OMB), has determined that this is not a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, no regulatory impact analysis is required.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. See 5 U.S.C. 603(a) and 604(a). The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 requires agencies to adjust civil penalties with an initial catch-up adjustment through an interim final rule. An interim final rule does not include first publishing a proposed rule. Thus, the RFA does not apply to this final rule.

C. Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2))

This rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of \$100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(č) Does not have significant adverse effects on competition, employment,

investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreignbased enterprises.

D. Unfunded Mandate Reform Act of 1995 (2 U.S.C. 1532)

This rule does not involve a Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more and that such rulemaking will not significantly or uniquely affect small governments.

E. E.O. 12630, Takings

This rule does not have takings implications.

F. E.O. 13132, Federalism

This rule does not have federalism implications. The rule does not 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.

G. E.O. 12988, Civil Justice Reform

This rule complies with the requirements of E.O. 12988. Specifically, this rule: (a) Does not unduly burden the

judicial system.

(b) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(c) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. E.O. 13175, Consultation With Indian Tribes

In accordance with Executive Order 13175, OPM has evaluated this rule and determined that it has no tribal implications.

I. Paperwork Reduction Act

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13.

List of Subjects in 5 CFR Part 185

Administrative practice and procedure, Claims, Fraud, Penalties.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

For the reasons set forth in the preamble, amend part 185 of title 5 of the Code of Federal Regulations as follows:

PART 185—PROGRAM FRAUD CIVIL REMEDIES: CIVIL MONETARY PENALTY INFLATION ADJUSTMENT

■ 1. The authority citation for part 185 is revised to read as follows:

Authority: 28 U.S.C. 2461 note; 31 U.S.C. 3801–3812.

§185.103 [Amended]

■ 2. Section 185.103 is amended as follows:

■ a. In paragraph (a) introductory text, remove "\$5,000" and add in its place "\$10,781".

■ b. In paragraph (f)(2), remove "\$5,000" and add in its place "\$10,781".

[FR Doc. 2016–17026 Filed 7–18–16; 8:45 am] BILLING CODE 6325–48–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 108

[Docket No. FDA-2015-N-2819]

Emergency Permit Control Regulations; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending certain regulations pertaining to registration and process filings related to acidified foods and thermally processed low-acid foods packaged in hermetically sealed containers (historically referred to as "low-acid canned foods" or "LACF"). The amendments reflect new FDA process filing form numbers, make changes to addresses or locations where such forms can be found or must be sent, remove obsolete references to the effective dates that occurred years ago, and update a reference to another Federal Agency.

DATES: This rule is effective August 18, 2016. See section VI for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by August 18, 2016.

ADDRESSES: You may submit objections and requests for a hearing as follows:

Electronic Submissions

Submit electronic objections in the following way:

• Federal eRulemaking Portal: http:// www.regulations.gov. Follow the