DEPARTMENT OF COMMERCE

Economic Development Administration

13 CFR Part 313

[Docket No.: 170828819–7819–01]

RIN 0610–AA70

Elimination of Regulations Implementing Community Trade Adjustment Assistance Program

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Final rule.

SUMMARY: Through this final rule, the Economic Development Administration (“EDA”), U.S. Department of Commerce, eliminates the regulations implementing the Community Trade Adjustment Assistance (“CTAA”) Program. Established in 2009 under the Trade Act of 1974, the CTAA Program was subsequently eliminated by Congress in 2011. Implementing regulations for this now-defunct Program are thus unnecessary. This final rule is a “deregulatory action” pursuant to the April 5, 2017, Office of Management and Budget (“OMB”) guidance memorandum implementing Executive Order 13771. Since the program is already defunct, there are no cost savings associated with this elimination.

Classification

Administrative Procedure Act and Regulatory Flexibility Act

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment are unnecessary. This rule removes obsolete regulations implementing the CTAA Program, which has been eliminated by Congress. Therefore, public comment would serve no purpose and is unnecessary. There is also good cause under 5 U.S.C. 553(b)(B) to waive the 30-day delay in effectiveness. This rule does not alter the rights or responsibilities of any party, and delaying implementation of this rule serves no purpose.

Because prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) are inapplicable. Therefore, a regulatory flexibility analysis has not been prepared.

Executive Orders No. 12866, 13563, and 13771

This final rule was drafted in accordance with Executive Orders 12866, 13563, and 13771. OMB has determined that this rule is not significant for purposes of Executive Orders 12866. This final rule is a “deregulatory action” pursuant to the April 5, 2017, OMB guidance memorandum implementing Executive Order 13771 (M–17–21).

Congressional Review Act

This final rule is not major under the Congressional Review Act (5 U.S.C. 801 et seq.).

Executive Order No. 13132

This final rule does not contain policies that have federalism implications.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq. (“PRA”)) requires that a Federal agency consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from OMB for each collection of information it conducts, sponsors, or requires through regulations. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the PRA unless that collection displays a currently valid OMB Control Number. This final rule does not require the collection of any information.

List of Subjects in 13 CFR Part 313

Trade adjustment assistance for communities, Impacted community, Petition and affirmative determination requirements, Strategic plan, Implementation grant.

For the reasons discussed above, and under the authority of 19 U.S.C. 2341–2372, EDA is removing and reserving 13 CFR part 313.

PART 313—[REMOVED AND RESERVED]


Dennis Alvard,
Deputy Assistant Secretary for Regional Affairs.

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NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Parts 1264 and 1271

RIN 2700–AE30


Implementation of the Federal Civil Penalties Inflation Adjustment Act and Adjustment of Amounts for 2017

AGENCY: National Aeronautics and Space Administration.
ACTION: Final rule.

SUMMARY: The National Aeronautics and Space Administration (NASA) has adopted as final the interim final rule concerning adjustments to civil monetary penalties within its jurisdiction for inflation. The interim rule was published on June 26, 2017, and applied a new methodology to calculate civil monetary penalties as mandated by the Federal Civil Penalties Adjustment Act Improvements Act of 2015, starting with an initial adjustment to previous unadjusted penalty amounts. The changes in the interim final rule made by this rule are effective October 20, 2017 and applicable as of August 25, 2017. In addition, this final rule provides for 2017 inflation adjustments of monetary penalties amounts required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES:
Effective: This final rule is effective October 20, 2017.
Applicable: This final rule is applicable as of August 25, 2017.

FOR FURTHER INFORMATION CONTACT: Bryan R. Diederich, Office of the General Counsel, NASA Headquarters, telephone (202) 358–0216.

SUPPLEMENTARY INFORMATION:

I. Background

A. The June 26, 2017, Interim Rule

The Inflation Adjustment Act, as amended by the 2015 Act, requires Federal agencies to adjust the civil penalty amounts within their jurisdiction for inflation by July 1, 2016, and then by January 15 every year thereafter. Agencies must make the initial 2016 adjustments through an interim final rulemaking published in the Federal Register. Under the amended Act, any increase in a civil penalty made under the Act will apply to penalties assessed after the increase takes effect, including penalties whose associated violation predated the increase. The inflation adjustments mandated by the Act serve to maintain the deterrent effect of civil penalties and to promote compliance with the law. On June 26, 2017, NASA published its interim final rule providing for the initial adjustment called for under the Act. The public comment period for the interim final rule closed on August 24, 2016, and the rule became effective on August 25, 2017. NASA received no comments on the interim final rule.

B. 2017 Inflation Adjustment

After the initial adjustment, the Act requires agencies to make subsequent annual adjustments for inflation “notwithstanding section 553 of title 5, United States Code.” Section 553 refers to the Administrative Procedure Act, which might otherwise require a delay for advance notice and opportunity for public comments on future annual inflation adjustments. The first of these subsequent adjustments is for 2017. Because of a delay in publishing NASA’s 2016 inflation adjustments as an interim final rule, the time for making the 2017 adjustment was reached while NASA was in the process of publishing its 2016 adjustments. Accordingly, in adopting as final the interim rule published on June 26, 2017, NASA is adjusting the penalty amounts to reflect the 2017 adjustments required by law.

The 2017 annual adjustments are based on the percent change between the U.S. Department of Labor’s Consumer Price Index for All Urban Consumers (“CPI–U”) for the month of October preceding the date of the adjustment, and the CPI–U for October of the prior year (28 U.S.C. 2461 note, section 5(b)(1)). Based on that formula, the cost-of-living adjustment multiplier for 2017 is 1.01636. Pursuant to the 2015 Act, adjustments are rounded to the nearest dollar.

II. The Final Rule

This rule makes final the interim final rule published June 26, 2017. In addition, this rule makes the required 2017 inflation adjustment. These adjusted amounts are reflected in the following table.

<table>
<thead>
<tr>
<th>Law</th>
<th>Penalty description</th>
<th>Penalty in June 26, 2017 interim rule</th>
<th>Penalty in 2017 inflation adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Fraud Civil Remedies Act of 1986</td>
<td>Maximum Penalties for False Claims</td>
<td>$10,781</td>
<td>$10,957</td>
</tr>
<tr>
<td>Department of the Interior and Related Agencies Appropriations Act of 1989, Public Law 101–121, sec. 319.</td>
<td>Minimum Penalty for use of appropriated funds to lobby or influence certain contracts.</td>
<td>18,936</td>
<td>19,246</td>
</tr>
<tr>
<td>Department of the Interior and Related Agencies Appropriations Act of 1989, Public Law 101–121, sec. 319.</td>
<td>Minimum Penalty for use of appropriated funds to lobby or influence certain contracts.</td>
<td>189,361</td>
<td>192,459</td>
</tr>
</tbody>
</table>

This rule codifies these civil penalty amounts by amending parts 1264 and 1271 of title 14 of the CFR.

III. Legal Authority and Effective Date

NASA issues this rule under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, and further amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which requires NASA to adjust the civil penalties within its jurisdiction for inflation according to a statutorily prescribed formula.

The Administrative Procedure Act (APA) generally requires an agency to publish a rule at least 30 days before its effective date. NASA’s publication of the June 26, 2017, interim final rule met the publication requirement in accordance with the APA.

1 See 28 U.S.C. 2461 note.
2 The statute also provides that, for the initial 2016 adjustment, an agency may adjust a civil penalty by less than the otherwise required amount if (1) it determines, after publishing a notice of proposed rulemaking and providing an opportunity for comment, that increasing the civil penalty by the otherwise required amount would have a negative economic impact or that the social costs of increasing the civil penalty by the otherwise required amount outweigh the benefits, and (2) the Director of the Office of Management and Budget concurs with that determination. Inflation Adjustment Act section 4(c), codified at 28 U.S.C. 2461 note. NASA has chosen not to make use of this exception.
this requirement. As explained above, the adjustments required for years subsequent to 2017 are not subject to the requirements of the Administrative Procedure Act. Moreover, the 2017 adjustments are made according to a statutory formula that does not provide for agency discretion. Accordingly, a delay in effectiveness of the 2017 adjustments is not required.

IV. Regulatory Requirements

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.9

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,10 NASA reviewed this interim final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the interim final rule.

List of Subjects in 14 CFR Parts 1264 and 1271

Claims, Lobbying, Penalties.

For the reasons stated in the preamble, the National Aeronautics and Space Administration adopts as final the interim rule amending 14 CFR parts 1264 and 1271 which published on June 26, 2017, at 82 FR 28760, with the following changes:

PART 1264—IMPLEMENTATION OF THE PROGRAM FRAUD CIVIL PENALTIES ACT OF 1986

1. The authority citation for part 1264 continues to read as follows:


§1264.102 [Amended]

2. In §1264.102, paragraphs (a) and (b), remove the number “$10,781” and add in its place the number “$10,957.”

PART 1271—NEW RESTRICTIONS ON LOBBYING

3. The authority citation for part 1271 continues to read as follows:


§1271.400 [Amended]

4. In §1271.400:

a. In paragraphs (a) and (b) remove the words “not less than $18,936 and not more than $189,361” and add in their place the words “not less than $19,246 and not more than $192,459.”

b. In paragraph (e), remove the two occurrences of “$18,936” and add in their place “$19,246” and remove “189,361” and add in its place “192,459”.

Appendix A to Part 1271 [Amended]

5. In appendix A to part 1271, in the paragraph following paragraph (3) and in the last paragraph of the appendix, remove the words “not less than $18,936 and not more than $189,361” and add in their place the words “not less than $19,246 and not more than $192,459”.

Nanette J. Smith,
NASA Federal Register Liaison Officer.

[FR Doc. 2017–22847 Filed 10–19–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2017–N–5371]

Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect and Identify Microbial Pathogen Nucleic Acids in Cerebrospinal Fluid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid into class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

Upon request, FDA has classified the device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360k) and part 807 (21 CFR part 807). FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After