

*C. Executive Order 13609, Promoting International Regulatory Cooperation*

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609 and has determined that this action will have no effect on international regulatory cooperation.

**X. Additional Information**

*A. Electronic Access*

Except for classified and controlled unclassified material not authorized for public release, all documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed from the internet through the docket for this rulemaking.

Those documents may be viewed online at <https://www.regulations.gov> using the docket number listed above. A copy of this rule will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at <https://www.federalregister.gov> and the Government Publishing Office's website at <https://www.govinfo.gov>. A copy may also be found at the FAA's Regulations and Policies website at [https://www.faa.gov/regulations\\_policies](https://www.faa.gov/regulations_policies).

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267-9677.

*B. Small Business Regulatory Enforcement Fairness Act*

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104-121) (set forth as a note to 5 U.S.C. 601) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official or the persons listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet,

visit [http://www.faa.gov/regulations\\_policies/rulemaking/sbre\\_act/](http://www.faa.gov/regulations_policies/rulemaking/sbre_act/).

**List of Subjects in 14 CFR Part 91**

Air traffic control, Aircraft, Airmen, Airports, Aviation safety, Freight, Syria.

**The Amendment**

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations, as follows:

**PART 91—GENERAL OPERATING AND FLIGHT RULES**

■ 1. The authority citation for part 91 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506-46507, 47122, 47508, 47528-47531, 47534, Pub. L. 114-190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.1609 by revising paragraph (e) to read as follows:

**§ 91.1609 Special Federal Aviation Regulation No. 114—Prohibition Against Certain Flights in the Damascus Flight Information Region (FIR) (OSTT).**

\* \* \* \* \*

(e) Expiration. This SFAR will remain in effect until December 30, 2028. The FAA may amend, rescind, or extend this SFAR, as necessary.

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f) and (g), 40101(d)(1), 40105(b)(1)(A), and 44701(a)(5).

**Michael Gordon Whitaker,**  
*Administrator.*

[FR Doc. 2023-28502 Filed 12-26-23; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF COMMERCE**

**Office of the Secretary**

**15 CFR Part 6**

**[Docket No. 231129-0280]**

**RIN 0605-AA66**

**Civil Monetary Penalty Adjustments for Inflation**

**AGENCY:** Office of the Chief Financial Officer and Assistant Secretary for Administration, Department of Commerce.

**ACTION:** Final rule.

**SUMMARY:** This final rule is being issued to adjust for inflation each civil monetary penalty (CMP) provided by law within the jurisdiction of the United

States Department of Commerce (Department of Commerce). The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, required the head of each agency to adjust for inflation its CMP levels in effect as of November 2, 2015, under a revised methodology that was effective for 2016 which provided for initial catch up adjustments for inflation in 2016, and requires adjustments for inflation to CMPs under a revised methodology for each year thereafter. The Department of Commerce's 2024 adjustments for inflation to CMPs apply only to CMPs with a dollar amount, and will not apply to CMPs written as functions of violations. The Department of Commerce's 2024 adjustments for inflation to CMPs apply only to those CMPs, including those whose associated violation predated such adjustment, which are assessed by the Department of Commerce after the effective date of the new CMP level.

**DATES:** This rule is effective January 15, 2024.

**FOR FURTHER INFORMATION CONTACT:**

Stephen M. Kunze, Deputy Chief Financial Officer and Director for Financial Management, Office of Financial Management, at (202) 482-1207, Department of Commerce, 1401 Constitution Avenue NW, Room D200, Washington, DC 20230. The Department of Commerce's Civil Monetary Penalty Adjustments for Inflation are available for downloading from the Department of Commerce, Office of Financial Management's website at the following address: [http://www.osec.doc.gov/ofm/OFM\\_Publications.html](http://www.osec.doc.gov/ofm/OFM_Publications.html).

**SUPPLEMENTARY INFORMATION:**

**Background**

The Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101-410; 28 U.S.C. 2461), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104-134), provided for agencies' adjustments for inflation to CMPs to ensure that CMPs continue to maintain their deterrent value and that CMPs due to the Federal Government were properly accounted for and collected.

A CMP is defined as any penalty, fine, or other sanction that:

1. Is for a specific monetary amount as provided by Federal law, or has a maximum amount provided for by Federal law; and,
2. Is assessed or enforced by an agency pursuant to Federal law; and,

3. Is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.

On November 2, 2015, the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Section 701 of Pub. L. 114–74) further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 to improve the effectiveness of CMPs and to maintain their deterrent effect. This amendment (1) required agencies to adjust the CMP levels in effect as of November 2, 2015, with initial catch up adjustments for inflation through a final rulemaking to take effect no later than August 1, 2016; and (2) requires agencies to make subsequent annual adjustments for inflation to CMPs that shall take effect no later than January 15. The Department of Commerce's 2023 adjustments for inflation to CMPs were published in the **Federal Register** on January 3, 2023, and the new CMP levels became effective January 15, 2023.

The Department of Commerce's 2024 adjustments for inflation to CMPs apply only to CMPs with a dollar amount, and will not apply to CMPs written as functions of violations. These 2024 adjustments for inflation apply only to those CMPs, including those whose associated violation predated such adjustment, which are assessed by the Department of Commerce after the effective date of the new CMP level.

This regulation adjusts for inflation CMPs that are provided by law within the jurisdiction of the Department of Commerce. The actual CMP assessed for a particular violation is dependent upon a variety of factors. For example, the National Oceanic and Atmospheric Administration's (NOAA) Policy for the Assessment of Civil Administrative Penalties and Permit Sanctions (Penalty Policy), a compilation of NOAA internal guidelines that are used when assessing CMPs for violations for most of the statutes NOAA enforces, will be interpreted in a manner consistent with this regulation to maintain the deterrent effect of the CMPs. The CMP ranges in the Penalty Policy are intended to aid enforcement attorneys in determining the appropriate CMP to assess for a particular violation. NOAA's Penalty Policy is maintained and made available to the public on NOAA's Office of the General Counsel, Enforcement Section website at: <https://www.noaa.gov/general-counsel/gc-enforcement-section>.

The Department of Commerce's 2024 adjustments for inflation to CMPs set forth in this regulation were determined pursuant to the methodology prescribed by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of

2015, which requires the maximum CMP, or the minimum and maximum CMP, as applicable, to be increased by the cost-of-living adjustment. The term "cost-of-living adjustment" is defined by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. For the 2024 adjustments for inflation to CMPs, the cost-of-living adjustment is the percentage for each CMP by which the Consumer Price Index for the month of October 2023 exceeds the Consumer Price Index for the month of October 2022.

#### Classification

Pursuant to 5 U.S.C. 553(b)(3)(B), there is good cause to issue this rule without prior public notice or opportunity for public comment because it would be unnecessary. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Section 701(b)) requires agencies to make annual adjustments for inflation to CMPs notwithstanding section 553 of title 5, United States Code. Additionally, the methodology used for adjusting CMPs for inflation is given by statute, with no discretion provided to agencies regarding the substance of the adjustments for inflation to CMPs. The Department of Commerce is charged only with performing ministerial computations to determine the dollar amounts of adjustments for inflation to CMPs. Accordingly, prior public notice and an opportunity for public comment are not required for this rule. For the same reasons, there is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date.

#### Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this rule because there are no new or revised recordkeeping or reporting requirements.

#### Regulatory Analysis

##### *E.O. 12866, Regulatory Review*

This rule is not a significant regulatory action as that term is defined in Executive Order 12866.

##### *Regulatory Flexibility Act*

Because notice of proposed rulemaking and opportunity for 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 is not required and has not been prepared.

#### List of Subjects in 15 CFR Part 6

Civil monetary penalties, Law enforcement.

Dated: December 20, 2023.

**Stephen M. Kunze,**

*Deputy Chief Financial Officer and Director for Financial Management, Department of Commerce.*

■ For the reasons stated in the preamble, the Department of Commerce revises 15 CFR part 6 to read as follows:

#### PART 6—CIVIL MONETARY PENALTY ADJUSTMENTS FOR INFLATION

Sec.

- 6.1 Definitions.
- 6.2 Purpose and scope.
- 6.3 Adjustments for inflation to civil monetary penalties.
- 6.4 Effective date of adjustments for inflation to civil monetary penalties.
- 6.5 Subsequent annual adjustments for inflation to civil monetary penalties.

**Authority:** Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 104–134, 110 Stat. 1321 (31 U.S.C. 3701 note); Sec. 701 of Pub. L. 114–74, 129 Stat. 599 (28 U.S.C. 1 note; 28 U.S.C. 2461 note).

##### § 6.1 Definitions.

(a) The *Department of Commerce* means the United States Department of Commerce.

(b) *Civil Monetary Penalty* means any penalty, fine, or other sanction that:

- (1) Is for a specific monetary amount as provided by Federal law, or has a maximum amount provided for by Federal law; and
- (2) Is assessed or enforced by an agency pursuant to Federal law; and
- (3) Is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.

##### § 6.2 Purpose and scope.

The purpose of this part is to make adjustments for inflation to civil monetary penalties, as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410; 28 U.S.C. 2461), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134) and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Section 701 of Pub. L. 114–74), of each civil monetary penalty provided by law within the jurisdiction of the United States Department of Commerce (Department of Commerce).

##### § 6.3 Adjustments for inflation to civil monetary penalties.

The civil monetary penalties provided by law within the jurisdiction of the Department of Commerce, as set forth in paragraphs (a) through (f) of this section, are hereby adjusted for inflation in

accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, from the amounts of such civil monetary penalties that were in effect as of January 15, 2023, to the amounts of such civil monetary penalties, as thus adjusted. The year stated in parenthesis represents the year that the civil monetary penalty was last set by law or adjusted by law (excluding adjustments for inflation).

(a) *United States Department of Commerce.* (1) 31 U.S.C. 3802(a)(1), Program Fraud Civil Remedies Act of 1986 (1986), violation, maximum from \$13,508 to \$13,946.

(2) 31 U.S.C. 3802(a)(2), Program Fraud Civil Remedies Act of 1986 (1986), violation, maximum from \$13,508 to \$13,946.

(3) 31 U.S.C. 3729(a)(1)(G), False Claims Act (1986); violation, minimum from \$13,508 to \$13,946; maximum from \$27,018 to \$27,894.

(b) *Bureau of Economic Analysis.* 22 U.S.C. 3105(a), International Investment and Trade in Services Act (1990); failure to furnish information, minimum from \$5,580 to \$5,761; maximum from \$55,808 to \$57,617.

(c) *Bureau of Industry and Security.* (1) 15 U.S.C. 5408(b)(1), Fastener Quality Act (1990), violation, maximum from \$55,808 to \$57,617.

(2) 22 U.S.C. 6761(a)(1)(A), Chemical Weapons Convention Implementation Act (1998), violation, maximum from \$45,429 to \$46,901.

(3) 22 U.S.C. 6761(a)(1)(B), Chemical Weapons Convention Implementation Act (1998), violation, maximum from \$9,086 to \$9,380.

(4) 50 U.S.C. 1705(b), International Emergency Economic Powers Act (2007), violation, maximum from \$356,579 to \$368,136.

(5) 22 U.S.C. 8142(a), United States Additional Protocol Implementation Act (2006), violation, maximum from \$36,919 to \$38,116.

(6) 50 U.S.C. 4819, Export Controls Act of 2018 (2018), violation, maximum from \$353,534 to \$364,992

(d) *Census Bureau.* (1) 13 U.S.C. 304, Collection of Foreign Trade Statistics (2002), each day's delinquency of a violation; total of not to exceed maximum per violation, from \$1,643 to \$1,696; maximum per violation, from \$16,438 to \$16,971.

(2) 13 U.S.C. 305(b), Collection of Foreign Trade Statistics (2002), violation, maximum from \$16,438 to \$16,971.

(e) *International Trade Administration.* (1) 19 U.S.C. 81s, Foreign Trade Zone (1934), violation, maximum from \$3,446 to \$3,558.

(2) 19 U.S.C. 1677f(f)(4), U.S.-Canada Free Trade Agreement Protective Order (1988), violation, maximum from \$247,929 to \$255,964.

(f) *National Oceanic and Atmospheric Administration.* (1) 51 U.S.C. 60123(a), Land Remote Sensing Policy Act of 2010 (2010), violation, maximum from \$13,625 to \$14,067.

(2) 51 U.S.C. 60148(c), Land Remote Sensing Policy Act of 2010 (2010), violation, maximum from \$13,625 to \$14,067.

(3) 16 U.S.C. 773f(a), Northern Pacific Halibut Act of 1982 (2007), violation, maximum from \$285,265 to \$294,510.

(4) 16 U.S.C. 783, Sponge Act (1914), violation, maximum from \$2,037 to \$2,103.

(5) 16 U.S.C. 957(d), (e), and (f), Tuna Conventions Act of 1950 (1962):

(i) Violation of 16 U.S.C. 957(a), maximum from \$101,805 to \$105,105.

(ii) Subsequent violation of 16 U.S.C. 957(a), maximum from \$219,273 to \$226,380.

(iii) Violation of 16 U.S.C. 957(b), maximum from \$3,446 to \$3,558.

(iv) Subsequent violation of 16 U.S.C. 957(b), maximum from \$20,362 to \$21,022.

(v) Violation of 16 U.S.C. 957(c), maximum from \$438,548 to \$452,761.

(6) 16 U.S.C. 957(i), Tuna Conventions Act of 1950,<sup>1</sup> violation, maximum from \$223,229 to \$230,464.

(7) 16 U.S.C. 959, Tuna Conventions Act of 1950,<sup>2</sup> violation, maximum from \$223,229 to \$230,464.

(8) 16 U.S.C. 971f(a), Atlantic Tunas Convention Act of 1975,<sup>3</sup> violation, maximum from \$223,229 to \$230,464.

(9) 16 U.S.C. 973f(a), South Pacific Tuna Act of 1988 (1988), violation, maximum from \$619,820 to \$639,908.

(10) 16 U.S.C. 1174(b), Fur Seal Act Amendments of 1983 (1983), violation, maximum from \$29,505 to \$30,461.

(11) 16 U.S.C. 1375(a)(1), Marine Mammal Protection Act of 1972 (1972), violation, maximum from \$34,457 to \$35,574.

(12) 16 U.S.C. 1385(e), Dolphin Protection Consumer Information Act,<sup>4</sup> violation, maximum from \$223,229 to \$230,464.

(13) 16 U.S.C. 1437(d)(1), National Marine Sanctuaries Act (1992), violation, maximum from \$210,161 to \$216,972.

<sup>1</sup>This National Oceanic and Atmospheric Administration maximum civil monetary penalty, as prescribed by law, is the maximum civil monetary penalty per 16 U.S.C. 1858(a), Magnuson-Stevens Fishery Conservation and Management Act civil monetary penalty (paragraph (f)(15) of this section).

<sup>2</sup> See footnote 1.

<sup>3</sup> See footnote 1.

<sup>4</sup> See footnote 1.

(14) 16 U.S.C. 1540(a)(1), Endangered Species Act of 1973:

(i) Violation as specified (1988), maximum from \$61,982 to \$63,991.

(ii) Violation as specified (1988), maximum from \$29,751 to \$30,715.

(iii) Otherwise violation (1978), maximum from \$2,037 to \$2,103.

(15) 16 U.S.C. 1858(a), Magnuson-Stevens Fishery Conservation and Management Act (1990), violation, maximum from \$223,229 to \$230,464.

(16) 16 U.S.C. 2437(a), Antarctic Marine Living Resources Convention Act of 1984,<sup>5</sup> violation, maximum from \$223,229 to \$230,464.

(17) 16 U.S.C. 2465(a), Antarctic Protection Act of 1990,<sup>6</sup> violation, maximum from \$223,229 to \$230,464.

(18) 16 U.S.C. 3373(a), Lacey Act Amendments of 1981 (1981):

(i) 16 U.S.C. 3373(a)(1), violation, maximum from \$31,908 to \$32,942.

(ii) 16 U.S.C. 3373(a)(2), violation, maximum from \$797 to \$823.

(19) 16 U.S.C. 3606(b)(1), Atlantic Salmon Convention Act of 1982,<sup>7</sup> violation, maximum from \$223,229 to \$230,464.

(20) 16 U.S.C. 3637(b), Pacific Salmon Treaty Act of 1985,<sup>8</sup> violation, maximum from \$223,229 to \$230,464.

(21) 16 U.S.C. 4016(b)(1)(B), Fish and Seafood Promotion Act of 1986 (1986); violation, minimum from \$1,350 to \$1,394; maximum from \$13,508 to \$13,946.

(22) 16 U.S.C. 5010, North Pacific Anadromous Stocks Act of 1992,<sup>9</sup> violation, maximum from \$223,229 to \$230,464.

(23) 16 U.S.C. 5103(b)(2), Atlantic Coastal Fisheries Cooperative Management Act,<sup>10</sup> violation, maximum from \$223,229 to \$230,464.

(24) 16 U.S.C. 5154(c)(1), Atlantic Striped Bass Conservation Act,<sup>11</sup> violation, maximum from \$223,229 to \$230,464.

(25) 16 U.S.C. 5507(a), High Seas Fishing Compliance Act of 1995 (1995), violation, maximum from \$193,890 to \$200,174.

(26) 16 U.S.C. 5606(b), Northwest Atlantic Fisheries Convention Act of 1995,<sup>12</sup> violation, maximum from \$223,229 to \$230,464.

<sup>5</sup> See footnote 1.

<sup>6</sup> See footnote 1.

<sup>7</sup>This National Oceanic and Atmospheric Administration maximum civil monetary penalty, as prescribed by law, is the maximum civil monetary penalty per 16 U.S.C. 1858(a), Magnuson-Stevens Fishery Conservation and Management Act civil monetary penalty (paragraph (f)(15) of this section).

<sup>8</sup> See footnote 7.

<sup>9</sup> See footnote 7.

<sup>10</sup> See footnote 7.

<sup>11</sup> See footnote 7.

<sup>12</sup> See footnote 7.

(27) 16 U.S.C. 6905(c), Western and Central Pacific Fisheries Convention Implementation Act,<sup>13</sup> violation, maximum from \$223,229 to \$230,464.

(28) 16 U.S.C. 7009(c) and (d), Pacific Whiting Act of 2006,<sup>14</sup> violation, maximum from \$223,229 to \$230,464.

(29) 22 U.S.C. 1978(e), Fishermen's Protective Act of 1967 (1971):

(i) Violation, maximum from \$34,457 to \$35,574.

(ii) Subsequent violation, maximum from \$101,805 to \$105,105.

(30) 30 U.S.C. 1462(a), Deep Seabed Hard Mineral Resources Act (1980), violation, maximum, from \$87,855 to \$90,702.

(31) 42 U.S.C. 9152(c), Ocean Thermal Energy Conversion Act of 1980 (1980), violation, maximum from \$87,855 to \$90,702.

(32) 16 U.S.C. 1827a, Billfish Conservation Act of 2012,<sup>15</sup> violation, maximum from \$223,229 to \$230,464.

(33) 16 U.S.C. 7407(b), Port State Measures Agreement Act of 2015,<sup>16</sup> violation, maximum from \$223,229 to \$230,464.

(34) 16 U.S.C. 1826g(f), High Seas Driftnet Fishing Moratorium Protection Act,<sup>17</sup> violation, maximum from \$223,229 to \$230,464.

(35) 16 U.S.C. 7705, Ensuring Access to Pacific Fisheries Act,<sup>18</sup> violation, maximum from \$223,229 to \$230,464.

(36) 16 U.S.C. 7805, Ensuring Access to Pacific Fisheries Act,<sup>19</sup> violation, maximum from \$223,229 to \$230,464.

(37) 16 U.S.C. 1857 note, James M. Inhofe National Defense Authorization Act for Fiscal Year 2023,<sup>20</sup> (newly reported penalty), violation, maximum \$230,464.

(g) *National Technical Information Service*. 42 U.S.C. 1306c(c), Bipartisan Budget Act of 2013 (2013), violation, minimum from \$1,158 to \$1,196; maximum total penalty on any person for any calendar year, excluding willful or intentional violations, from \$289,504 to \$298,887.

(h) *Office of the Under Secretary for Economic Affairs*. 15 U.S.C. 113, Concrete Masonry Products Research, Education, and Promotion Act of 2018, violation, maximum from \$5,000 to \$5,162.

#### **§ 6.4 Effective date of adjustments for inflation to civil monetary penalties.**

The Department of Commerce's 2024 adjustments for inflation made by § 6.3,

of the civil monetary penalties there specified, are effective on January 15, 2024, and said civil monetary penalties, as thus adjusted by the adjustments for inflation made by § 6.3, apply only to those civil monetary penalties, including those whose associated violation predated such adjustment, which are assessed by the Department of Commerce after the effective date of the new civil monetary penalty level, and before the effective date of any future adjustments for inflation to civil monetary penalties thereto made subsequent to January 15, 2024 as provided in § 6.5.

#### **§ 6.5 Subsequent annual adjustments for inflation to civil monetary penalties.**

The Secretary of Commerce or his or her designee by regulation shall make subsequent adjustments for inflation to the Department of Commerce's civil monetary penalties annually, which shall take effect not later than January 15, notwithstanding section 553 of title 5, United States Code.

[FR Doc. 2023-28484 Filed 12-26-23; 8:45 am]

**BILLING CODE 3510-DP-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 202**

**Docket No. FDA-2009-N-0582]**

#### **Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format Final Rule: Questions and Answers; Guidance for Industry; Small Entity Compliance Guide; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a guidance for industry entitled "Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format Final Rule: Questions and Answers." We are issuing this small entity compliance guide (SECG) in accordance with the Small Business Regulatory Enforcement Fairness Act to help small businesses understand and comply with the "Direct-to-Consumer

Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format Final Rule" (CCN Final Rule). The CCN Final Rule modifies FDA regulations to reflect the requirement in the Federal Food, Drug, and Cosmetic Act (FD&C Act) that human prescription drug advertisements presented directly to consumers (DTC) in television or radio format and stating the name of the drug and its conditions of use (DTC TV/radio ads) present the major statement relating to side effects and contraindications (major statement) in a clear, conspicuous, and neutral manner and establishes standards to help ensure this requirement is met. The term "drugs" in this guidance refers to prescription human drug and biological products.

**DATES:** The announcement of the guidance is published in the **Federal Register** on December 27, 2023.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and

<sup>13</sup> See footnote 7.

<sup>14</sup> See footnote 7.

<sup>15</sup> See footnote 7.

<sup>16</sup> See footnote 7.

<sup>17</sup> See footnote 7.

<sup>18</sup> See footnote 7.

<sup>19</sup> See footnote 7.

<sup>20</sup> See footnote 7.