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

(28) 16 U.S.C. 7009(c) and (d), Pacific Whiting Act of 2006,[14] 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,[15] violation, maximum from $223,229 to $230,464.

(33) 16 U.S.C. 7407(b), Port State Measures Agreement Act of 2015,[16] violation, maximum from $223,229 to $230,464.

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

(35) 16 U.S.C. 7705, Ensuring Access to Pacific Fisheries Act,[18] violation, maximum from $223,229 to $230,464.

(36) 16 U.S.C. 7805, Ensuring Access to Pacific Fisheries Act,[19] 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,[20] (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

[13] See footnote 7.
[14] See footnote 7.
[15] See footnote 7.
[16] See footnote 7.
[17] See footnote 7.
[18] See footnote 7.
[19] See footnote 7.
[20] See footnote 7.

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

Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2009–N–0582 for ''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.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the SECG to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Suzanna Boyle, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3214, Silver Spring, MD 20993–0002, 301–796–1200, *CDER-OPDP-RPM@fda.hhs.gov;* or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

We are 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.'' FDA is issuing this SECG as a level 2 guidance, consistent with FDA's good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). Consistent with the GGP regulation, FDA is immediately implementing the level 2 guidance and inviting public comment (§ 10.115(g)(4)).

We are issuing this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28) to help small businesses understand and comply with the CCN Final Rule (88 FR 80958, November 21, 2023). The CCN Final Rule modifies 21 CFR 202.1(e)(1) to reflect the requirement in section 502(n) of the FD&C Act (21 U.S.C. 352(n)) 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 in a clear, conspicuous, and neutral manner. The CCN Final Rule also establishes standards to help ensure that this requirement is met.

This guidance addresses the content and effect of the CCN Final Rule, including identifying which drugs and advertisements are covered by the rule. The term ''drugs'' in this guidance refers to prescription human drug and biological products. In addition, this guidance explains when firms are expected to comply with the CCN Final Rule and how they can do so. The term ''firms'' in this guidance refers to manufacturers, packers, and distributors of any human prescription drug that, in any State, is distributed or offered for sale and who advertise that drug, and to all persons who they cause to issue any advertisement with respect to their human prescription drug(s), including both individuals and corporate entities.

This level 2 guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The SECG represents the current thinking of FDA on how small businesses can better 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 or Radio Format Final Rule.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 202.1 have been approved under OMB control number 0910–0686. The collections of information in 21 CFR 314.81(b)(3)(i) relating to the submission of advertisements and promotional labeling have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the SECG at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA websites listed in the previous sentence to find the most current version of the guidance.

Dated: December 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28530 Filed 12–26–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

[ED–2023–OSERS–0177]

Final Waiver and Extension of the Project Period With Funding for Innovative Rehabilitation Training Grants

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education.

ACTION: Final waiver and extension of project period with funding.

SUMMARY: The Secretary waives the requirements in the Education Department General Administrative Regulations that generally prohibit project periods exceeding five years and project period extensions involving the obligation of additional Federal funds. The waiver and extension enable seven projects under Assistance Listing Number (ALN) 84.263C to receive funding for an additional period, not to exceed September 30, 2025.

DATES: The waiver and extension of the project periods are effective December 27, 2023.

FOR FURTHER INFORMATION CONTACT: Felipe Lulli, U.S. Department of Education, 400 Maryland Avenue SW, Room 4A110, Washington, DC 20202. Telephone: 202–987–0128. Email: *Felipe.Lulli@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Background

On October 3, 2023, the Department published a notice in the **Federal Register** (84 FR 32135) proposing a waiver and extension of the project period with funding in order to enable seven projects under Assistance Listing Number (ALN) 84.263C to receive continuation funding for an additional 12-month period, not to exceed September 30, 2025. The proposed waiver and extension of the project period with funding would allow the Department to align those dates with that of awards funded under ALNs 84.263E and 84.263F, which will each receive their final year of funding in FY 2024, and end on September 30, 2025. Due to the overlapping goals of these three programs, the Department does not believe that it would be in the public interest to run a competition for ALN 84.263C in FY 2024. Rather, aligning the projects' periods of performance end dates for ALNs 84.263C, 84.263E, and 84.263F would reduce financial and administrative burden by allowing the Department to conduct a single competition for all 84.263C, 84.263E, and 84.263F grants in FY 2025, with a five-year performance period that would run from October 1, 2025, through September 30, 2030.

There are no differences between the notice of proposed waiver and extension of the project period with funding and this notice of final waiver and extension of the project period with funding, as discussed in the *Analysis of Comments and Changes* section of this document.

Public Comment

In response to our invitation in the notice of proposed waiver and extension of the project period with funding, two parties submitted comments.

Generally, we do not address technical and other minor changes or suggested changes the law does not authorize us to make under the applicable statutory authority. In addition, we do not address general comments that raised concerns not directly related to the proposed waiver and extension with funding.

Analysis of Comments and Changes

An analysis of the comments and of any changes in the priority since publication of the notice of proposed waiver and extension of the project period with funding follows.

Comment: One commenter expressed strong support for the proposed waiver and extension of the project period with funding noting the vital importance of the Innovation Rehabilitation Training projects to the Vocational Rehabilitation field. The commenter described first-hand experience serving on an advisory board of one of the Innovative Rehabilitation Training grants and evaluating their products. The commenter noted the value of the products to the vocational rehabilitation field in meeting the needs of individuals with disabilities.

Discussion: The Department appreciates support for the proposed waiver and extension of the project period with funding for the Innovative Rehabilitation Training grants.

Change: None.

Comment: One commenter analyzed whether the proposed waiver and extension of the project period with funding would lead to more efficient outcomes for the Innovative Rehabilitation Training program. The commenter presented one argument that extending the project period and providing additional funding would offer the Department streamlined decision-making and grantee flexibility to ensure the delivery of comprehensive, high-quality training that effectively meets the needs of their target populations. The commenter presented a counterargument that extending the project timeline might cause grantees to delay project milestones if they know extensions are readily available, leading to inefficiencies and prolonged timelines that do not guarantee improved outcomes. The commenter recommended the Department implement appropriate oversight procedures to alleviate possible risks and safeguard the effectiveness of the waiver and extension of the project period to alleviate financial and administrative burden.

Discussion: The Department appreciates the commenter's analysis of arguments for and against the proposed notice of waiver and extension of the project period with funding and carefully considered them in its decision making. The Department will monitor grantees in accordance with applicable regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99; (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485; and (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. Additionally, the Department will assess grant performance through annual reporting and tracking of expenditures to ensure that project milestones for both the current budget period and the additional budget period