DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 11

[Docket No. FDA–2019–N–0646]

Change of Address; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: Before using an electronic signature in an electronic record required by the Food and Drug Administration (FDA or Agency), a person must submit a letter of non-repudiation to FDA. Letters of non-repudiation are required to certify that a person's electronic signatures are intended to be the legally binding equivalent of traditional handwritten signatures. FDA is amending its regulations to update the address for submission of a certification in paper form and to provide an option for electronic submission. This amendment is to ensure accuracy and clarity in the Agency's regulations. This technical amendment is nonsubstantive.

DATES: This rule is effective March 2, 2023.

FOR FURTHER INFORMATION CONTACT: Elizabeth L. Kunkoski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3332, Silver Spring, MD 20993–0002, *elizabeth.kunkoski@fda.hhs.gov,* 301–796–6439.

SUPPLEMENTARY INFORMATION: Before using an electronic signature in an electronic record required by FDA, a person must submit a letter of non-repudiation to FDA (§ 11.100(c) 21 CFR 11.100(c)). Letters of non-repudiation are required under § 11.100(c)(1) to certify that a person's electronic signatures are intended to be the legally binding equivalent of traditional handwritten signatures. FDA is amending its regulations in 21 CFR part 11 to update the address for submission of a certification in paper form and to provide an option for electronic submission. The new addresses are as follows:

- *For certification of electronic signatures for submissions sent through FDA's Electronic Submissions Gateway Program, submit to: ESGHelpDesk@fda.hhs.gov;* or
- *For certification of electronic signatures for submissions not submitted through FDA's Electronic Submissions Gateway Program, submit to:* Jessica Bernhardt, Electronic Submissions Gateway, U.S. Food and Drug Administration, 3WFN, Rm. 7C34, 12225 Wilkins Ave., Rockville, MD 20852.

Information on where to submit the certification is currently found on FDA's web page on Letters of Non-Repudiation Agreement at *https://www.fda.gov/industry/about-esg/appendix-g-letters-non-repudiation-agreement.* This action is being taken to ensure accuracy and clarity in the Agency's regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment makes only technical or non-substantive, ministerial changes to reflect a change in electronic submission capabilities and corrects the address for submission of a non-repudiation letter. Such technical, non-substantive changes are ''routine determination[s], insignificant in nature and impact, and inconsequential to the industry and to the public.'' (*Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012)) (quotation marks and citation omitted). Accordingly, FDA for good cause finds that notice and public procedure thereon are unnecessary for these changes in where and how the certification is submitted.

In addition, we find good cause for these amendments to become effective on the date of publication of this action. The APA allows an effective date of less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, we find good cause for this correction to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 11

Computer technology, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 11 is amended as follows:

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 1. The authority citation for part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 2. In § 11.100, revise paragraph (c)(1) to read as follows:

§ 11.100 General requirements.

* * * * *

(c) * * *

(1) The certification shall be signed with a traditional handwritten signature and submitted in electronic or paper form. Information on where to submit the certification can be found on FDA's web page on Letters of Non-Repudiation Agreement.

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Dated: February 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04010 Filed 3–1–23; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Parts 140, 141, 211, 213, 225, 226, 227, 243, and 249

[234A2100DD/AAKC001030/A0A501010.999900253G]

RIN 1076–AF74

Civil Penalties Inflation Adjustments; Annual Adjustments

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: This rule provides for annual adjustments to the level of civil monetary penalties contained in Bureau of Indian Affairs (Bureau) regulations to account for inflation under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget (OMB) guidance.

DATES: This rule is effective on March 2, 2023.

FOR FURTHER INFORMATION CONTACT: Oliver Whaley, Director, Office of Regulatory Affairs and Collaborative Action (RACA), Office of the Assistant Secretary—Indian Affairs; Department of the Interior, telephone (202) 738–6065, *RACA@bia.gov.*

SUPPLEMENTARY INFORMATION: