4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. FDA-2023-N-0986]

Change of Address; Technical Amendment

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is amending its regulations to update the address, email address, and office name for the Office of Policy, Legislation, and International Affairs, Office of Global Policy and Strategy. This technical amendment is to ensure accuracy and clarity in the Agency's regulations and is nonsubstantive.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Jeff Nelligan, Office of Global Policy and Strategy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 3438, Silver Spring, MD 20993, 301-796-8814, Jeff.Nelligan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending 21 CFR part 312 to update the name of an office, its physical address, and instructions for sending certifications via email. Publication of this document constitutes final action on the changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to update organizational information.

List of Subjects in 21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and

recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 312 is amended as follows:

PART 312--INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

2. In § 312.110, revise paragraph (b)(4) introductory text to read as follows:

§ 312.110 Import and export requirements.

* * * * *

(b) * * *

(4) Except as provided in paragraph (b)(5) of this section, the person exporting the drug sends an email certification to the Office of Global Policy and Strategy at OGPSExecSec@fda.hhs.gov, or a written certification to the Office of Global Policy and Strategy (HFG-1), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 3420, Silver Spring, MD 20993, at the time the drug is first exported and maintains records documenting compliance with this paragraph (b)(4). The certification shall describe the drug that is to be exported (i.e., trade name (if any), generic name, and dosage form), identify the country or countries to which the drug is to be exported, and affirm that:

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Dated: March 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-06260 Filed: 3/24/2023 8:45 am; Publication Date: 3/27/2023]