

Commission will vote on the Authority's proposed budget no later than November 1.

(b) *Conditional collection of fees allowed.* The notice required to be sent to State racing commissions estimating the amount required from each State for the subsequent year must state that the amount required is based on the proposed annual budget, as approved by the Board of Directors, which takes effect only if approved by the Commission. The State racing commissions (or covered persons in States that do not elect to remit fees) may nevertheless elect to remit fees, and the Authority may conditionally collect them, even before the Commission approves the proposed budget. If the Commission makes any modifications to line items under paragraph (d) of this section that have the net effect of reducing the budget, the Authority must refund any State racing commission or covered person that has conditionally paid by the proportionate amount owed within 30 days. If the Commission makes any modifications to line items under paragraph (d) of this section that have the net effect of increasing the budget, the Authority may obtain loans to make up the difference or may account for the difference as a funding shortfall incurred in the subsequent year's proposed budget.

(c) *Decisional criteria.* The Commission will approve the proposed budget if the Commission determines that, on balance, the proposed budget serves the goals of the Horseracing Integrity and Safety Act in a prudent and cost-effective manner, utilizing commercially reasonable terms with all outside vendors, and that its anticipated revenues are sufficient to meet its anticipated expenditures.

(d) *Modification of line items.* In its decision on the proposed budget, the Commission may modify the amount of any line item.

(e) *Public comments.* Public comments on the Authority's proposed budget should provide commenters' views as to the decisional criteria and whether any line items should be modified.

§ 1.152 Deviation from approved budget.

(a) *When notice to the Commission is required.* The Authority may deviate from the approved budget's expenditure information in a year as to any line item by up to 10 percent in a year. If the Authority determines that it is likely to expend more than the approved expenditure of any line item by 10 percent or more, or if it will exceed its approved total expenditure by any amount, it must notify the Commission

immediately upon such a determination.

(b) *Line-item deviations of more than 10 percent.* If the Authority determines that it is likely to expend more than the approved expenditure of any line item by 10 percent or more, its notice to the Commission must indicate whether it intends to repurpose funds from one or more different line items to cover the increased expenditure. The Commission retains the discretion to disapprove such a proposed repurposing. The Commission must issue any decision to disapprove a proposed repurposing within 7 business days of receiving notice of the Authority's proposal to repurpose funds from another line item. If the Commission takes no action, the Authority's proposal takes effect as an amendment to its approved budget.

(c) *Total expenditure deviation.* If the Authority determines that it is likely to expend more than the total approved expenditure, its notice to the Commission must indicate by what means it proposes to cover the difference. The Commission retains the discretion to disapprove the proposed means of covering the difference. The Commission must issue any decision to disapprove a proposed means of covering the difference within 7 business days of receiving notice of the Authority's proposal to cover the difference. If the Commission takes no action, the Authority's proposal takes effect as an amendment to its approved budget.

By direction of the Commission,
Commissioner Wilson not participating.

April J. Tabor,

Secretary.

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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 March 27, 2023.

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:

* * * * *

Dated: March 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-06260 Filed 3-24-23; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 548

Belarus Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is adopting a final rule amending and reissuing the Belarus Sanctions Regulations to implement an August 9, 2021 Belarus-related Executive order and incorporate a directive regarding sovereign debt issued pursuant to the August 9, 2021 Belarus-related Executive order. This rule also updates and adds new definitions, updates and adds general licenses, and updates interpretative guidance, among other changes.

DATES: This rule is effective March 27, 2023.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202-622-2480; Assistant Director for Regulatory Affairs, 202-622-4855; or Assistant Director for Sanctions Compliance & Evaluation, 202-622-2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: www.treas.gov/ofac.

Background

On February 3, 2010, OFAC issued the Belarus Sanctions Regulations, 31 CFR part 548 (75 FR 5502, February 3, 2010) (the "Regulations"), to implement Executive Order (E.O.) 13405 of June 16, 2006, "Blocking Property of Certain Persons Undermining Democratic Processes or Institutions in Belarus" (71 FR 35485, June 20, 2006), pursuant to authorities delegated to the Secretary of the Treasury in E.O. 13405. OFAC

subsequently amended the Regulations twice. OFAC is amending and reissuing the Regulations to implement E.O. 14038 of August 9, 2021, "Blocking Property of Additional Persons Contributing to the Situation in Belarus" (86 FR 43905, August 11, 2021). In addition, this rule incorporates one directive issued pursuant to E.O. 14038. Due to the number of regulatory sections being updated or added, OFAC is reissuing the Regulations in their entirety.

E.O. 14038. On August 9, 2021, the President, invoking the authority of, *inter alia*, the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), issued E.O. 14038. In E.O. 14038, the President expanded the scope of the national emergency declared in E.O. 13405, finding that the Belarusian regime's harmful activities and long-standing abuses aimed at suppressing democracy and the exercise of human rights and fundamental freedoms in Belarus—including illicit and oppressive activities stemming from the August 9, 2020, fraudulent Belarusian presidential election and its aftermath, such as the elimination of political opposition and civil society organizations and the regime's disruption and endangering of international civil air travel—constituted an unusual and extraordinary threat to the national security and foreign policy of the United States.

Section 1 of E.O. 14038 blocks, with certain exceptions, all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any United States person of any person determined by the Secretary of the Treasury, in consultation with the Secretary of State to: (i) be or have been a leader, official, senior executive officer, or member of the board of directors of: (A) an entity that has, or whose members have, engaged in any of the activities described in section 1(a)(v) of E.O. 14038 or sections 1(a)(ii)(A)–(C) of E.O. 13405; or (B) an entity whose property and interests in property are blocked pursuant to E.O. 14038 or E.O. 13405; (ii) be a political subdivision, agency, or instrumentality of the Government of Belarus; (iii) be or have been a leader or official of the Government of Belarus; (iv) operate or have operated in the defense and related materiel sector, security sector, energy sector, potassium chloride (potash) sector, tobacco products sector, construction sector, or transportation sector of the economy of Belarus, or any other sector of the Belarus economy as may be determined

by the Secretary of the Treasury, in consultation with the Secretary of the State; (v) be responsible for or complicit in, or to have directly or indirectly engaged or attempted to engage in, any of the following: (A) actions or policies that threaten the peace, security, stability or territorial integrity of Belarus; (B) actions or policies that prohibit, limit, or penalize the exercise of human rights and fundamental freedoms (including freedoms of expression, peaceful assembly, association, religion or belief, and movement) by individuals in Belarus, or that limit access to the internet or print, online, or broadcast media in Belarus; (C) electoral fraud or other actions or policies that undermined the electoral process in a Republic of Belarus election; (D) deceptive or structured transactions or dealings to circumvent any United States sanctions by or for or on behalf of, or for the benefit of, directly or indirectly, the Government of Belarus or any person whose property and interests in property are blocked pursuant to E.O. 14038 or E.O. 13405; or (E) public corruption related to Belarus; (vi) have materially assisted, sponsored, or provided financial material, or technological support for, or goods or services to or in support of, any activity described in section (a)(v) of E.O. 14038 or any person whose property and interests in property are blocked pursuant to E.O. 14038; or (vii) be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, the Government of Belarus or any person whose property and interests in property are blocked pursuant to E.O. 14038. The property and interests in property of the persons described above may not be transferred, paid, exported, withdrawn, or otherwise dealt in.

Section 2 of E.O. 14038 provides that the prohibitions on any transaction or dealing in blocked property or interests in property include the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 14038, and the receipt of any contribution or provision of funds, goods, or services from any such person.

In section 3 of E.O. 14038, the President determined that the making of donations of the type of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)) by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to E.O. 14038 would seriously impair the President's ability to deal with the national emergency declared in