

2023 season. A reduction in the operational volume at the New York airports would also aid in reducing the severity of significant NAS impact days.

In addition, because New York-DCA is a high frequency market for multiple carriers, the FAA recognizes this market is a likely target for carriers to consolidate flights while retaining their network connectivity. If carriers choose to reduce their schedules in the New York-DCA market, the FAA encourages carriers to utilize their DCA slots to operate to other destinations, to the extent that is practical. However, if carriers are unable to utilize their DCA slots elsewhere, it would be necessary to provide relief to DCA slots that are impacted by the reduction in operations at the New York airports.

Finally, carriers should be aware that the N90 staffing shortfalls will not form a sufficient basis for relief going forward because carriers will have had sufficient opportunity to plan and take remedial action under this waiver policy. The FAA does not foresee providing additional *post-hoc* relief associated with ATC staffing given the extraordinary relief provided here. Given this relief, operational impacts associated with N90 staffing during the summer 2023 scheduling season will not have been beyond the carriers control and will not serve as a valid basis for a waiver.

Decision

The FAA has determined the post-pandemic effects on N90 staffing meets the applicable waiver standards and warrants a limited waiver of minimum slot usage requirements at JFK and LGA to allow carriers to return up to 10 percent of their slots at each airport voluntarily as well as impacted operations between DCA and the New York airports. In addition, the FAA has determined the post-pandemic effects on N90 staffing warrants a limited policy for prioritizing returned operations at EWR to allow carriers to return 10 percent of their approved operating timings voluntarily, for purposes of establishing a carrier's operational baseline in the next corresponding season. Carriers wishing to return their slots and approved operating timings voluntarily must do so before April 30, 2023 to be eligible for this waiver. If carriers participating in this limited waiver at EWR subsequently operate unapproved flights at that airport, those carriers will forfeit their scheduling preference to an equal number of returned approved operating timings chosen at the FAA's discretion for the subsequent equivalent traffic season. Additionally, any other

relief from minimum slot usage requirements or standard level 2 processes already in effect at JFK, LGA, or EWR will factor into the 10 percent of allowable returns. In other words, any returns made under a relief policy already in effect when this notice is published will count towards the carrier's 10 percent of allowable returns. Further, the FAA encourages carriers to up-gauge aircraft serving the affected airports to the extent possible to maintain passenger throughput and minimally impact consumers.

The FAA will not reallocate the returned slots or approved operating timings at JFK, LGA, or EWR, as the goal is to reduce the volume of operations in the New York region. Carriers are encouraged to utilize their DCA slots in other markets before returning them to the FAA. In the event DCA slots are returned under this waiver, other carriers will have an opportunity to operate the slots on an *ad hoc* basis without historic precedence to serve markets other than New York.

The FAA will treat as used the specific slots returned in accordance with the conditions in this document for the period from May 15, 2023, through September 15, 2023. The relief is subject to the following conditions:

1. The specific slots and approved operating timings must be returned to the FAA before April 30, 2023.
2. This waiver applies only to slots that have corresponding, scheduled operations during the period of the grant. A carrier temporarily returning a slot to FAA for relief under this waiver must identify corresponding scheduled operation. FAA may validate information against published schedule data as of March 14, 2023, and other operational data maintained by FAA. Slots returned without an associated scheduled and cancelled operation will not receive relief.
3. Slots or approved operating timings newly allocated for initial use before October 28, 2023, are not eligible for relief.
4. Slots authorized at DCA by Department of Transportation or FAA exemptions are not eligible for relief.

Issued in Washington, DC, on March 22, 2023.

Marc A. Nichols,
Chief Counsel.

Alyce Hood-Fleming,
Vice President, System Operations Services.
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FEDERAL TRADE COMMISSION

16 CFR Part 1

Procedures for Oversight of the Horseracing Integrity and Safety Authority's Annual Budget

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission ("Commission") is issuing rules pursuant to the Horseracing Integrity and Safety Act ("Act") to provide procedures for the Commission's oversight of the annual budget of the Horseracing Integrity and Safety Authority ("Authority").

DATES: This rule is effective on March 27, 2023.

FOR FURTHER INFORMATION CONTACT: John H. Seesel (202-326-2702), Office of the General Counsel, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: The Horseracing Integrity & Safety Act,¹ enacted on December 27, 2020, and amended on December 29, 2022, directs the Federal Trade Commission to oversee the activities of a private, self-regulatory organization called the Horseracing Integrity and Safety Authority.

The Act, in subsection 15 U.S.C. 3052(f), sets forth certain requirements for the Authority's budget. On the revenue side, as for initial funding, the Authority is to obtain loans,² and generally it "may borrow funds toward the funding of its operations."³ After the program effective date of July 1, 2022, the Authority performs an annual calculation of the "amount required" from each State in which covered horseracing takes place, which estimates the amount required from each State "to fund the State's proportionate share of the horseracing anti-doping and medication control program and the racetrack safety program for the next calendar year" and "to liquidate the State's proportionate share of any loan or funding shortfall."⁴ The amount required by each State is calculated under the Assessment Methodology rule⁵ and must be "based on," among

¹ 15 U.S.C. 3051 through 3060.

² See 15 U.S.C. 3052(f)(1)(A).

³ *Id.* 3052(f)(1)(B).

⁴ *Id.* 3052(f)(1)(C)(i).

⁵ The Assessment Methodology proposed rule was published in the **Federal Register** and approved by the Commission after a period of public comment. See Fed. Trade Comm'n, Notice of HISA Assessment Methodology Proposed Rule, 87 FR 9349 (Feb. 28, 2022), <https://www.federalregister.gov/documents/2022/02/18/2022-03717/hisa-assessment-methodology-rule> (containing the

other things, “the annual budget of the Authority for the following calendar year.”⁶

On the expenditure side of the budget, the Act provides that the “initial budget” requires approval by a two-thirds supermajority of the Authority’s Board of Directors, as does any “subsequent budget that exceeds the budget of the preceding calendar year by more than 5 percent.”⁷ The Act has two more relevant provisions: “A proposed increase in the amount required under this subparagraph”—in other words, the Authority’s budget—“shall be reported to the Commission.”⁸ And: “The Commission shall publish in the **Federal Register** such a proposed increase and provide an opportunity for public comment.”⁹

The Act does not specify whether the Authority’s proposed budget takes effect upon the closing of the public-comment period or whether the Commission is to consider the public comments and then decide whether to approve or disapprove the Authority’s proposed budget. On the one hand, the Authority’s budget is not listed among the eleven enumerated items in 15 U.S.C. 3053(a) that “shall not take effect unless . . . approved by the Commission.”¹⁰ On the other hand, what the Authority submits (in the event of an increase in the amount required) is a “*proposed* increase,” which implies that a Commission decision to approve or disapprove the proposal will follow.¹¹ Although the Act does not identify criteria by which the Commission should evaluate the

Authority’s proposed budget, in December 2022 Congress conferred on the Commission the power to issue rules “as the Commission finds necessary or appropriate to ensure the fair administration of the Authority . . . or otherwise in furtherance of the purposes of this Act.”¹²

The Commission hereby exercises this newly granted rulemaking authority to clarify the Commission’s role in approving and overseeing the Authority’s budget, as well as the public’s role in providing comment, and to set forth clear requirements as to the Authority’s budget. Specifically, the Commission adds a new subpart U to part 1 of its Rules of Practice, to provide procedures for the Commission’s oversight of the Authority’s budget.¹³

I. Section 1.150—Authority’s Proposed Budget Submissions

Section 1.150 provides for the Authority’s proposed annual budget to use the calendar year as its fiscal year and to be submitted to the Commission by September 1 of the preceding year. The submission of the proposed budget is required regardless of whether the Authority’s budget contains a “proposed increase in the amount required” as compared to the previous year.¹⁴ The Commission believes that its oversight of the Authority’s budget is best performed consistently rather than only when the amount required increases. In short, annual rather than less-frequent budget oversight is a baseline requirement “to ensure the fair administration of the Authority.”¹⁵ The Authority’s submission must contain: an indication of the vote of its Board of Directors; sufficient revenue and expenditure information, broken out by line item, as would be required for members of the Board of Directors to exercise their fiduciary duty of care; and a comparison of the current year’s actual revenues and expenditures with those that were approved. The submission should address the Commission’s budget approval decision criteria: that 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. If the

Commission determines that the proposed budget as submitted satisfies the requirements, the Commission will publish the proposed budget in the **Federal Register** for 14 days of public comment.

In addition, and notwithstanding the September 1 deadline for submission of the Authority’s next year’s budget to the Commission, § 1.150 requires the Authority to post its anticipated budget for the following year as early as is practicable in the preceding year. The Authority’s posting of its planned next year’s budget shall include an invitation to the public to submit comments to the Authority concerning any aspect of the planned annual budget. The Authority is required to post those public comments as they arrive on its website and to review the comments in order to ascertain whether to revise the budget in any manner. Further, § 1.150 requires the Authority to promptly provide the public comments that it receives to the Commission, together with an assessment of such public comments that the Authority believes would assist the Commission’s evaluation of the planned budget.

II. Section 1.151—Commission Decision on Authority’s Proposed Budget

Section 1.151 provides that the Authority’s proposed budget takes effect only if approved by the Commission. This provision mirrors others in the Act that require proposals made by the Authority, such as for rules and rule modifications, to receive Commission approval before they take effect. For ease of administration and to account for the time the Commission may take to render a decision on the proposed budget, the Authority is permitted to conditionally collect fees, and State racing commissions (and covered persons in States that do not elect to remit fees) are permitted to pay, based on the annual budget as approved by the Authority’s Board of Directors.

The criteria by which the Commission will decide whether to approve or disapprove the Authority’s proposed budget are in § 1.151(c), which provides that the Commission will approve the proposed budget if the Commission determines, on balance, the proposed budget serves the goals of the Act in a prudent and cost-effective manner, utilizing commercially reasonable terms with all outside vendors, and anticipated revenues are sufficient to meet its anticipated expenditures. With respect to revenues and expenditures, the Commission may also modify any line item. The Commission will publish the Authority’s proposed budget in the **Federal Register** for 14 days of public

text of the Assessment Methodology proposed rule as submitted by the Authority); Fed. Trade Comm’n, Order Approving the Assessment Methodology Rule Proposed by the Horseracing Integrity & Safety Auth., at 1 (Apr. 1, 2022), available at https://www.ftc.gov/system/files/ftc_gov/pdf/Order%20re%20HISA%20Assessment%20Methodology.pdf. The Authority later submitted a proposed rule modification to Assessment Methodology, which was also published in the **Federal Register** and approved by the Commission after a period of public comment. See Fed. Trade Comm’n, Notice of HISA Assessment Methodology Proposed Rule Modification, 87 FR 67915 (Nov. 10, 2022), <https://www.federalregister.gov/documents/2022/11/10/2022-24609/hisa-assessment-methodology-rule-modification>; Fed. Trade Comm’n, Order Approving the Assessment Methodology Rule Modification Proposed by the Horseracing Integrity & Safety Auth., at 1 (Jan. 9, 2023), available at https://www.ftc.gov/system/files/ftc_gov/pdf/order_re_hisa_assessment_methodology_modification_not_signed_002_0.pdf.

⁶ 15 U.S.C. 3052(f)(1)(C)(ii)(I)(aa).
⁷ *Id.* 3052(f)(1)(C)(iii)(I), (II). Implicitly, subsequent budgets that do not exceed by more than 5 percent the budget of the preceding calendar year require only a simple majority of the Authority’s Board of Directors.

⁸ *Id.* 3052(f)(1)(C)(iv)(I).

⁹ *Id.* 3052(f)(1)(C)(iv)(II).

¹⁰ *Id.* 3053(b)(2).

¹¹ *Id.* 3052(f)(1)(C)(iv)(I), (II) (emphasis added).

¹² Consolidated Appropriations Act, 2023, H.R. 2617, 117th Cong., Division O, Title VII (2022) (to be codified at 15 U.S.C. 3053(e)).

¹³ In addition, the Commission intends in the near future to engage in further rulemaking prescribing oversight of non-budgetary aspects of the Authority’s operations.

¹⁴ 15 U.S.C. 3052(f)(1)(C)(iv).

¹⁵ *Id.* 3053(e).

comment. Public comments are welcomed as to both whether the submission satisfies the Commission's decisional criteria and whether the Commission should modify any line items.

III. Section 1.152—Deviation From Approved Budget

Section 1.152 sets forth what happens in circumstances in which actual revenues or expenditures deviate from those approved in the annual budget. When the Authority determines that, for a given expenditure's line item, the actual expenditure is likely to exceed the approved expenditure by more than 10 percent, it must immediately notify the Commission. Such a notice must indicate whether the Authority proposes to repurpose money from the line item of another expenditure to make up the difference for the expenditure whose likely actual amount will exceed the approved amount. So, too, when the Authority determines that its overall expenditures will exceed its approved expenditures, it must immediately notify the Commission. Such a notice must indicate the means by which the Authority intends to make up the difference, such as obtaining loans. For both overall-expenditure and line-item deviations, the Commission retains the right to disapprove the proposed repurposing or means of making up the difference, which it must do within seven business days of receiving the Authority's notice. If the Commission takes no action, the Authority's proposal takes effect as an amendment to its budget.

Because these rules relate solely to agency procedure and practice, publication for notice and comment is not required under the Administrative Procedure Act. 5 U.S.C. 553(b).¹⁶

List of Subjects in 16 CFR Part 1

Administrative practice and procedure.

For the reasons set forth in the preamble, the Federal Trade Commission amends title 16, chapter I, subchapter A of the Code of Federal Regulations as follows:

PART 1—GENERAL PROCEDURES

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

Authority: 15 U.S.C. 46; 15 U.S.C. 57a; 5 U.S.C. 552; 5 U.S.C. 601 note.

¹⁶ For this reason, the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601(2), 604(a), are also inapplicable. Likewise, the amendments do not modify any FTC collections of information within the meaning of the Paperwork Reduction Act, 44 U.S.C. 3501 through 3521.

■ 2. Add subpart U to read as follows:

Subpart U—Procedures for Oversight of the Horseracing Integrity and Safety Authority's Annual Budget

Sec.

1.150 Authority's proposed budget submissions.

1.151 Commission's decision on Authority's proposed budget.

1.152 Deviation from approved budget.

§ 1.150 Authority's proposed budget submissions.

(a) *Mandatory annual submission.* The Authority must submit a proposed annual budget to the Commission every year, irrespective of whether there is a "proposed increase in the amount required" under 15 U.S.C. 3052(f)(1)(C)(iv). The submission of the proposed budget for the following year must be made by September 1 of the current year, following the procedures set forth in § 1.143. The Authority's annual budget will use the calendar year as its fiscal year.

(b) *Public comments.* In addition to submitting its planned budget to the Commission by September 1 of the preceding year, the Authority shall post such planned budget on its own website as early as is practicable, with an invitation to the public to submit comments to the Authority on any aspect of the planned next year's budget. The Authority shall post such comments on its website upon their arrival and shall review them to ascertain whether to revise the budget in any manner. In addition, the Authority shall promptly forward to the Commission:

(1) Any such public comments that it receives; and

(2) An assessment of such public comments that it believes would assist the Commission's evaluation of the Authority's planned budget.

(c) *Contents of submission—(1) Indication of Board vote.* The Authority's proposed budget must be approved by a majority of its Board of Directors (or, in the case of its initial budget or a budget that exceeds the preceding year's budget by 5 percent or more, a two-thirds supermajority) and must state the Board vote on the motion to approve the budget.

(2) *Revenue information.* The proposed budget must identify both the estimated amount required from each State racing commission as calculated under 15 U.S.C. 3052(f) and all other sources of Authority revenue as well as any loans proposed to be obtained by the Authority.

(3) *Expenditure information.* The proposed budget must identify expenditures separately for:

- (i) The racetrack safety program;
- (ii) The anti-doping and medication control program;
- (iii) All other programmatic expenditures other than for racetrack safety and anti-doping and medication control, such as the administration of the Authority or its technological needs;
- (iv) Repayment of any loans; and
- (v) Any funding shortfall incurred.

(4) *Line items.* For both revenue and expenditure information, the Authority's proposed budget must provide sufficient information, by line item, as would be required for members of the Authority's Board of Directors to exercise their fiduciary duty of care. For example, the proposed budget's expenditure information for anti-doping and medication control might include separate line items for in-house salaries, the costs of testing of laboratory samples, the costs of arbitrators, and all the costs associated with contracting with an anti-doping and medication control enforcement agency. The proposed budget must include a narrative component that provides a brief explanation of each line item's utility in carrying out the purposes of the Horseracing Integrity and Safety Act.

(5) *Comparison of approved budget to actual revenues and expenditures.* The proposed budget must provide a comparison showing, for each approved line item, the actual revenues and expenditures for the current year along with a narrative component explaining why any line item is anticipated to deviate by 10 percent or more during the current year.

(d) *Approval and publication of submission.* The Commission will publish the Authority's proposed budget in the **Federal Register** if the Commission determines that the proposed budget contains sufficient information for the members of the Board of Directors of the Authority to exercise their fiduciary duty of care and meets the requirements of this subpart. Members of the public will then have 14 days in which to file comments on the proposed budget.

§ 1.151 Commission's decision on Authority's proposed budget.

(a) *Commission approval required.* The Authority's proposed budget takes effect only if approved by the Commission. The Commission will approve or disapprove the proposed budget after considering the public comments filed and the Commission's internal review per the submission requirements in § 1.150. The

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.

[FR Doc. 2023-06023 Filed 3-24-23; 8:45 am]

BILLING CODE 6750-01-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 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