Issued in College Park, Georgia, on August 12, 2024

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Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2024–18298 Filed 8–15–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 129

International Aviation Safety Assessment (IASA) Program

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Suspension of policy statement.

SUMMARY: On September 28, 2022, the FAA published a Policy Statement in the **Federal Register** that described policy changes to the FAA's International Aviation Safety Assessment (IASA) program as well as clarification or restatement of prior policy to ''enhance engagement with civil aviation authorities (CAAs) through pre- and post-IASA assessment and to promote greater transparency.'' After receiving inquiries and questions about the changes described in that policy statement, the FAA is suspending implementation of the September 28, 2022, Policy Statement while the agency reassesses the policy. The policy statement published March 8, 2013, remains active.

DATES: The policy statement published at 87 FR 58725 (September 28, 2022) is suspended as of August 16, 2024.

FOR FURTHER INFORMATION CONTACT: Rolandos Lazaris, Division Manager, International Program Division (AFS–50), Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; (202) 267–3719.

SUPPLEMENTARY INFORMATION:

Background

The IASA program is the means by which the FAA determines whether another country's oversight of its air carriers that (1) operate, or seek to operate, services to/from the United States using their own aircraft and crews, or (2) seek to display the code of a U.S. air carrier on any services, complies with safety standards established by the International Civil Aviation Organization (ICAO). The published IASA results of a country's placement in Category 1 or Category 2 is the notification to the U.S. traveling public as to whether a foreign air carrier's homeland civil aviation authority meets ICAO safety standards. A Category 1 rating indicates that the civil aviation authority meets ICAO safety standards for these operations, and a Category 2 rating indicates that the civil aviation authority does not meet ICAO safety standards. The IASA program was established by a document published in the **Federal Register** in 1992. Subsequent published documents in the **Federal Register** notified of the program's evolution. These **Federal Register** documents are as follows:

- August 24, 1992—Established the FAA Procedures for Examining and Monitoring Foreign Air Carriers (57 FR 38342).
- September 8, 1994—Established the Public Disclosure of the Results of Foreign Civil Aviation Authority Assessments, through a three-category numbered rating system (59 FR 46332).
- October 31, 1995—DOT Notice Clarification Concerning Examination of Foreign Carriers' Request for Expanded Economic Authority, clarified the Department's licensing policy regarding requests for expanded economic authority from foreign air carriers whose CAA's safety oversight capability has been assessed by the FAA as conditional (Category II) or unacceptable (Category III) (60 FR 55408).
- May 25, 2000—Changes to the International Aviation Safety Assessment program removed the Category 3 rating and combined it with Category 2 (65 FR 33751).
- March 8, 2013—Changes to the International Aviation Safety Assessment program removed inactive countries (countries with no air carrier operations to the United States or code-shares with U.S. air carrier for four years and no significant interaction between the country's CAA and the FAA) from the IASA Category list (78 FR 14912).

Through the IASA program, the FAA seeks continuous improvement to global aviation safety. As noted in the above-referenced policy statement of September 8, 1994, initial IASA assessments found that two-thirds of the assessed CAAs were deficient in meeting their safety oversight obligations under the Convention on International Civil Aviation.

The September 28, 2022, Policy Statement (87 FR 58725) (now suspended) announced certain changes to the IASA program and provided clarification to other aspects of the IASA policy. Since that publication, the FAA and DOT have received inquiries and questions that warrant reassessment of those changes and clarifications, and an opportunity for public comment before they are adopted permanently. As noted above, the FAA is suspending implementation of the September 28, 2022, Policy Statement while the agency reassesses the policy and considers public comments. Public comment is invited on the matters and issues described in the companion document published elsewhere in this issue of the **Federal Register**.

Issued in Washington, DC.

Jodi L. Baker,

Deputy Administrator for Aviation Safety.

[FR Doc. 2024–16954 Filed 8–15–24; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 1

RIN 3084–AB79

Horseracing Integrity and Safety Authority Oversight

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') is issuing a final rule (''Final Rule'') regarding oversight of the Horseracing Integrity and Safety Authority (''Authority''). The Final Rule includes new oversight provisions to ensure that the Authority remains publicly accountable and operates in a fiscally prudent, safe, and effective manner.

DATES: This rule is effective on September 16, 2024.

FOR FURTHER INFORMATION CONTACT: Sarah Botha, (202) 326–2036, *sbotha@ftc.gov,* Office of the Executive Director, Federal Trade Commission.

SUPPLEMENTARY INFORMATION: This document states the basis and purpose for the Commission's decision to adopt the Final Rule addressing the Commission's oversight of the Authority. The new oversight provisions were proposed and published for public comment in the **Federal Register** on February 8, 2024, in a notice of proposed rulemaking (''NPRM'').[1] After careful review and consideration of the entire record on the issues presented in this rulemaking proceeding, including 10 comments submitted by interested parties, the Commission has decided to adopt, with a few modifications, the proposed new oversight rule.

[1] FTC, Horseracing Integrity and Safety Authority Oversight, Proposed Rule, 89 FR 8578 (Feb. 8, 2024).

I. Background

The Horseracing Integrity and Safety Act of 2020 (''HISA'' or ''the Act''), Public Law 116–260, Title XII, 134 Stat. 1182, 3252 (2020) (codified as amended at 15 U.S.C. 3051–3060), recognizes the Authority as a self-regulatory nonprofit organization charged with developing and enforcing rules relating to racetrack safety, anti-doping, and medication control. *See* 15 U.S.C. 3052. The Act expressly provides for Commission oversight of several aspects of the Authority's operations. For example, the Commission must approve any proposed rule or rule modification by the Authority relating to the Authority's bylaws, racetrack safety standards, anti-doping and medication control, and the formula or methodology for determining assessments. *See* 15 U.S.C. 3053. In December 2022, Congress amended HISA to expand the Commission's oversight role over the Authority. *See* Consolidated Appropriations Act, 2023, Public Law 117–328, sec. 701, 136 Stat. 4459, 5231 (2022). As amended, the Act gives the Commission the power to issue rules under the procedures set forth in the Administrative Procedure Act, 5 U.S.C. 553, ''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.'' 15 U.S.C. 3053(e).

II. Overview of the Proposed Oversight Rule

In light of the Commission's experience in overseeing the Authority's operations to date, the Commission proposed several new rule provisions to ensure effective Commission oversight over the Authority. The proposed provisions were designed to ensure that the Authority is promoting transparency and integrity in its operations. For example, the proposed new rule sections would require the Authority to submit and publish annual and midyear reports about its performance and financial position. The proposed new rules would also require the Authority to develop, maintain, and publish a multiyear strategic plan, after taking public comments on a draft plan. The proposed rules would require the Authority to effectively manage risk and take steps to prevent conflicts of interest, waste, fraud, embezzlement, and abuse. The proposed rules would also mandate other operational requirements and identify best practices for the Authority to follow.

Section-by-Section Analysis

Section 1.153 Submission of the Authority's annual reports, midyear reports, and strategic plans. This proposed new section would impose certain requirements on the Authority to report on its finances for the preceding calendar year by May 15. This would include a complete accounting of the Authority's budget (as audited by a qualified, independent, registered public accounting firm and in accordance with Generally Accepted Accounting Principles), a discussion of budgetary line items, a summary of travel expenses, and a summary of any new or continuing risks or issues raised by audits or other reviews. The proposed section also would impose certain requirements on the Authority to report by March 31 on its performance for the prior calendar year. The report would include efforts made to carry out the requirements of the Act, a description of the cooperation with the States as set forth in 15 U.S.C. 3060(b), a summary of final civil sanctions, an assessment of the Authority's progress in meeting or not meeting its performance measures contained in its strategic plan per § 1.153(d), and a summary of Board of Directors committee recommendations and activities. It would also include information about any changes in the composition of the Authority's Board of Directors or standing committees, information about the relationship between the Authority and the anti-doping and medication control enforcement agency, a summary of all litigation to which the Authority is a party (including actions commenced by the Authority under 15 U.S.C. 3054(j)), a summary of all subpoenas issued by the Authority under 15 U.S.C. 3054(c), a description of any areas in which the Authority believes improvements to its operations are warranted, and the Authority's plans to achieve those improvements. The proposed section would also require the Authority to submit to the FTC by August 15 a same-year midyear report covering January to June that describes spending and staffing levels and budgetary information. This midyear report would provide operational insight about the Authority's budget execution and risk management activities. The proposed section would have also required the Authority to develop and publish for public comment a multiyear strategic plan by June 30, 2024. The Authority would be required to re-evaluate its strategic plan no less frequently than every five years. The strategic plan must align with the Authority's annual budget, discuss its priority initiatives, and set forth a set of performance measures. The Authority would be required publish its annual financial reports, annual performance reports, and strategic plans on its website.

Section 1.154 Enterprise risk management. This proposed new section would impose certain requirements on the Authority to ensure that it effectively manages risk to prevent conflicts of interest, waste, fraud, embezzlement, or abuse. Paragraph (a) sets forth guiding principles around separation of duties and corrective action plans, and noted that risk management activities must ensure compliance, the avoidance of conflicts of interest or the appearance thereof, and the appropriate handling of funds received and expended by the Authority. Given the confidential nature of much of the Authority's work and the data that it collects, Paragraph (b) would require the Authority to ensure the privacy and security of its data in its systems, including those operated by third-party contractors, and require a complete annual evaluation of the status of its overall information technology program and practices as audited by a qualified, independent, third-party auditor. Given that the Authority leverages contractor resources in its operations, Paragraph (c) would require the Authority to document its market research for any action estimated at over $10,000 to ensure the lowest cost or best value for goods and services to be provided, and to develop policies and procedures covering procurement activities. Given the FTC's need for regular communication and awareness of the Authority's activities, Paragraph (d) would require the Authority to provide advance notice to Commission staff of all significant Authority-planned events (*e.g.,* press conferences, media events, summits, etc.) via a calendar, list, email, or other reasonable means, to summarize key aspects of all such events on its website, and to give Commission staff prompt notice after significant adverse events in the horseracing industry that might reasonably lead to sanctions or track closures.

Section 1.155 Other best practices. This proposed new section included a set of best practices to promote accountability, transparency of operations, and effective resource stewardship of the Authority. These proposals included holding regular monitoring meetings with the FTC; recommendations for how the Authority may maintain its records and information; recommendations for how the Authority should treat confidential information; a standing data request from the FTC for the Authority's Board of Directors minutes; recommendations

about the Authority's personnel and compensation policies and practices; recommendations about the Authority's customer service program (and the development of associated metrics); and recommendations regarding the Authority's travel policies.

Section 1.156 Severability. This proposed new section noted that provisions of this subpart are separate and severable from one another. If any provision is stayed or determined to be invalid, it is the Commission's intention that the remaining provisions would continue in effect.

III. Overview of Public Comments Received in Response to the NPRM

The Commission received 10 comments in response to the NPRM,[2] representing the views of an industry trade group, individuals and groups concerned with animal welfare issues, attorneys who have represented clients in Authority enforcement actions, and individuals with an interest in the horseracing industry. The Authority also submitted a comment in which it responded to the comments filed in response to the NPRM and shared its views regarding the proposed rule.

The majority of the comments focused on the FTC's proposed oversight rule, but three comments addressed topics related to the Authority's rules or suggested other areas that the Commission should consider for rulemaking.[3] The remaining comments expressed support for the proposed rule,[4] but some comments also submitted suggestions for additional or amended rule provisions.

One comment, submitted by two attorneys who have represented Covered Persons in enforcement actions brought under the Authority's rules, stated that increased scrutiny of the Authority by the FTC is needed and welcomed, but urged the Commission to include additional requirements for the Authority, such as public disclosure of all contracts, travel expenses, and line item costs for hearings.[5] The Commission appreciates the commenters' suggestions but believes the proposed rule strikes the right balance between mandating the disclosure of information to bring greater transparency and accountability to the Authority's operations without depleting limited resources with overly burdensome disclosure requirements. The rule will require the Authority to publish on its website annual financial and performance reports providing significant details regarding the Authority's expenditures and operations, along with a multiyear strategic plan that is developed with public input. Existing Commission rules require further information to be submitted annually during the budget review process, which the Commission publishes in the **Federal Register**, and the Commission can seek additional information through its process of reviewing and approving the Authority's budget.[6]

Another commenter expressed support for the proposed rule, but opined that the rule provisions fall short in the area of enforcement.[7] The commenter seems to be under the impression that the Authority has exempted sales companies and breeders from the application of 15 U.S.C. 3059. That statutory provision says that in connection with the sale of Covered Horses (or horses anticipated to be covered), it is a violation of section 5 of the FTC Act, 15 U.S.C. 45, to fail to make certain disclosures. *See* 15 U.S.C. 45(a) (prohibiting ''unfair or deceptive acts or practices in or affecting commerce''). Section 5, however, is enforced only by the FTC, not the Authority. Another section of HISA does permit the Authority to refer matters to the Commission and recommend that the Commission pursue an enforcement action under 15 U.S.C. 3059. *See* 15 U.S.C. 3054(c)(2). The discretion to pursue such an action, however, rests solely with the Commission.

Another commenter believed that the proposed rule would be greatly beneficial to the horseracing industry but opined that the rule was ''lacking in the enforcement of best practices'' and should include penalties for violations of the rule in order to incentivize compliance.[8] The Commission fully expects that the Authority will comply with the Final Rule, and that the Authority would seek a modification from the Commission if there were any provisions in the rule that the Authority anticipated would present compliance difficulties. In fact, the Authority has filed a comment expressing its thoughts on the proposed rule and requesting some minor changes to the rule, as discussed below. To date, the Authority has complied with the rules the Commission has promulgated addressing submissions to the FTC under the Act,[9] review of final civil sanctions,[10] and review of the Authority's annual budget.[11] The Commission fully anticipates that the Authority will comply with the Final Rule.

A comment from the National Horsemen's Benevolent & Protective Association (''NHBPA'') supported the Commission's goal to bring transparency to the Authority's operations, but opined that the proposed rule is not authorized by the Act.[12] Specifically, the NHBPA posited that 15 U.S.C. 3053(e) allows the FTC to initiate rules to ''abrogate, add to, [or] modify the rules of the Authority promulgated in accordance with [HISA],'' but that the proposed rule does not abrogate, add to, or modify the Authority's rules and is therefore unauthorized by the Act.[13] The Commission disagrees that it lacks statutory authority to promulgate the proposed rule.

The proposed rule is in accordance with 15 U.S.C. 3053(e). Congress provided there that ''[t]he Commission, by rule in accordance with'' the Administrative Procedure Act, ''may . . . add to . . . the rules of the Authority promulgated in accordance with'' HISA ''as the Commission finds necessary or appropriate to ensure the

[2] All comments submitted can be found at *www.regulations.gov* under Docket ID FTC–2024–0012. We cite public comments by name of the commenting organization or individual and the comment number.

[3] *See* Anonymous 5 (seeking the expansion of rules and regulations for animal welfare, cruelty and abuse); Lange 6 (requesting a change in the Authority's rules addressing eligibility requirements for Covered Horses); WhoPoo App 9 (asking the FTC to mandate that all horseracing venues include a horse/equine rescue allotment and fund).

[4] *See, e.g.,* Bell 2 (expressing support for actions to improve the integrity of the governing of horseracing, and opining that Congress authorized the FTC to engage in this rulemaking); Humane Society of the United States and Humane Society Legislative Fund 12 (noting that ''increased transparency will be integral to ensuring the safety and welfare of horses and jockeys, and key to monitoring effective enforcement of the Horseracing Integrity and Safety Act'').

[5] Fisco 7. The commenters also opined on several existing rules of the Authority, which are beyond the scope of this rulemaking.

[6] *See* 16 CFR 1.151(a).

[7] Roberts 4. The commenter also opined on several existing rules of the Authority, which are beyond the scope of this rulemaking.

[8] Newcomer 11. The commenter also criticized the rule for failing to address the treatment of horses by parties involved in horseracing. This falls outside the scope of this rulemaking. The Authority, however, has rules that address the topics raised by the commenter, including the humane treatment of equine athletes and bans on performance-enhancing drugs, and all of the commenters are encouraged to file comments on those rules when proposed modifications are published by the Authority or by the Commission. *See, e.g.,* FTC, Horseracing Integrity and Safety Authority Anti-Doping and Medication Control Rule Modification, proposed rule modification, 88 FR 65683 (Sept. 25, 2023); FTC, Horseracing Integrity and Safety Authority Racetrack Safety Rule Modification, proposed rule modification, 89 FR 24574 (Apr. 8, 2024).

[9] 16 CFR 1.140 through 1.144.

[10] 16 CFR 1.145 through 1.149.

[11] 16 CFR 1.150 through 1.152.

[12] NHBPA 8.

[13] *Id.*

fair administration of the Authority . . . or otherwise in furtherance of the purposes of [the Act].'' 15 U.S.C. 3053(e). The proposed rule ''add[s] to'' the rules that the Authority has promulgated in accordance with the Act and does so ''to ensure the fair administration of the Authority . . . or otherwise in furtherance of the purposes of [the Act].'' *Id.* The plain text of HISA thus authorizes the Commission to promulgate the proposed rule.[14]

Apart from its belief that Congress would be the appropriate entity to promulgate the proposed rule, the NHBPA stated that it ''supports the substance behind'' proposed §§ 1.153, 1.154, and 1.155, including the requirements for an annual financial report with an independent audit, an annual performance report with summaries of the Authority's enforcement activities, a multiyear strategic plan, and enterprise risk management activities.[15]

Finally, the Authority submitted a comment in which it responded to some of the public comments submitted in response to the NPRM and suggested some modifications to the rule as proposed.[16] Specifically, the Authority requested that the deadline for submitting the first annual financial report under § 1.153(a) be changed from May 15, 2024, to June 17, 2024. This request is now moot.

The Authority also requested that the annual deadline for submitting a same-year midyear report under § 1.153(c) be changed from August 15 to August 30, to ''provide adequate time for the CFO to complete this report after the proposed budget is submitted to the Commission.'' [17] Under the FTC's Rules, the Authority's proposed annual budget for the following year must be submitted to the Commission by August 1 each year,[18] and the Commission must approve or disapprove the proposed budget by November 1, or as soon thereafter as practicable, after publishing the proposed budget for public comment.[19] The Commission believes that the midyear report required under § 1.153(c) will inform the Commission's consideration of the Authority's proposed budget for the following year and that delaying the submission of the midyear report would hinder the Commission's ability to fully consider the report prior to voting on the proposed budget. The Commission's need for the midyear report outweighs the Authority's need for an extension and, for this reason, the Authority's request is denied and the proposed reporting deadline of August 15 is retained in the Final Rule.

The Authority requested that the submission deadline for the initial multiyear strategic plan under § 1.153(d) be changed from June 30, 2024, to August 30, 2024.[20] In order to permit the Authority sufficient time to publish its draft strategic plan for public comment and finalize the plan subsequent to the effective date of the Final Rule, the Commission has changed the deadline for submission of the initial multiyear strategic plan to October 15, 2024.

The Authority requested that the documented market research requirement for procurement actions required under § 1.154(c) be applicable to procurement actions estimated at over $50,000, rather than (as proposed) procurement actions estimated at over $10,000.[21] The Commission does not believe that documenting market research for procurement actions estimated at over $10,000 will be unreasonably burdensome, so it declines this request.

The Authority requested that the recommendation of § 1.155(d) for the Authority to submit Board of Directors minutes to the Commission's Office of the Secretary be changed from within 15 days following each Board meeting to within 30 days following each Board meeting, to provide adequate time for the Board minutes to be prepared and approved by the Board.[22] The Commission finds this request to be reasonable and has changed the recommended submission deadline in the Final Rule to within 30 days following each Board meeting.

Finally, regarding the recommendation in § 1.155(g) that the Authority ''use standard, GSA [General Services Administration]-established, published per diem rates when determining how much a person may spend on lodging, meals, and incidental expenses,'' the Authority commented that it ''does not receive government lodging rates and therefore, the Authority does not believe that the use of standard GSA-established, published per diem rates will be practical.'' [23] The Commission believes that the travel policy recommendation in the proposed rule is reasonable, and has retained it in the Final Rule.[24] The Commission notes that the recommendation also states, ''Nevertheless, actual subsistence expenses may be authorized under unusual circumstances with justification and prior approval from the appropriate approving official.'' This recommendation is similar to GSA regulations that apply to Federal agencies.[25] The Authority's travel policy should specify what rate it will use when authorizing travel, and the Final Rule recommends that rate should be based upon standard, GSA-established, published per diem rates. The Authority could, however, establish a policy whereby it authorizes the standard, GSA-established, published per diem rates for mileage reimbursement and for meals and incidental expenses, while basing its rate for lodging on the GSA rate with allowances for deviations from that rate within a certain range. For example, the Authority could require that lodging be within the GSA-established rate but, if an employee cannot find a room within that rate, the Authority could allow lodging to exceed the GSA-established rate by up to 300 percent, as necessary and with approval from a designated official.

IV. The Final Rule

In this document, the Commission adopts the proposed new provisions as final, with the two minor changes discussed above. The Final Rule also adds references in § 1.153(c) and (d) to following the procedures in § 1.143 for submissions to the Commission and, in this way, mirrors § 1.153(a) and (b) and clarifies the applicable submissions requirements. The Final Rule also clarifies that the midyear reporting requirement in § 1.153(c) is an annual one.

The Commission is adding the Final Rule as 16 CFR 1.153 through 1.156 in subpart U of part 1 of its Rules of Practice. Subpart U is therefore renamed ''Oversight of the Horseracing Integrity and Safety Authority'' to more accurately reflect the content of the amended subpart.

V. Paperwork Reduction Act

The Paperwork Reduction Act (''PRA''), 44 U.S.C. chapter 35, requires

[14] The NHBPA opined that the Act prohibits the FTC from promulgating a proposed rule unless the Authority has ''already adopted a rule *on the topic.*'' *Id.* (emphasis added). That supposed limitation on the Commission's authority is nowhere in the plain text of the statute.

[15] NHBPA 8.

[16] Horseracing Integrity and Safety Authority 10.

[17] *Id.*

[18] *See* 16 CFR 1.150(a).

[19] *See* 16 CFR 1.150(d) and 1.151(a).

[20] Horseracing Integrity and Safety Authority 10.

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] Government per diem rates are updated annually at *https://www.gsa.gov/travel,* and available to Authority staff to refer to.

[25] *See* 41 CFR 301–11.30 (''What is my option if the Government lodging rate exceeds my lodging reimbursement? . . . You may request reimbursement on an actual expense basis, not to exceed 300 percent of the maximum per diem allowance.'').

Federal agencies to seek and obtain Office of Management and Budget approval before undertaking a collection of information directed to ten or more persons. Under the PRA, a rule creates a ''collection of information'' when ten or more persons are asked to report, provide, disclose, or record information in response to ''identical questions.'' [26] The Commission concludes that the PRA does not apply to the amendments because they only apply to one ''person,'' the Authority.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA''), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires an agency to either provide a Final Regulatory Flexibility Analysis with a final rule, or certify that the rule will not have a significant impact on a substantial number of small entities.[27] The RFA defines a ''small entity'' as a small business, a small governmental jurisdiction, or a small not-for-profit organization. *See* 5 U.S.C. 601(6).

The Final Rule applies only to the Authority, and the Authority is not a small business or a small governmental jurisdiction. While the Authority is a nonprofit entity, it is not a small not-for-profit organization, defined in the RFA as ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' *Id.* 601(5). The Authority is not ''independently owned and operated,'' and it is dominant in its field. The Commission therefore certifies under the RFA that the Final Rule will not have a significant economic impact on a substantial number of small entities, and hereby provides notice of that certification to the Small Business Administration.

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

List of Subjects in 16 CFR Part 1

Administrative practice and procedure, Animal drugs, Animal welfare.

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:

[26] 44 U.S.C. 3502(3)(A).

[27] 5 U.S.C. 603–605.

PART 1—GENERAL PROCEDURES

Subpart U—Oversight of the Horseracing Integrity and Safety Authority

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

Authority: 15 U.S.C. 3053(e).

■ 2. Revise the heading for subpart U to read as set forth above.

■ 3. Add §§ 1.153 through 1.156 to subpart U to read as follows:

* * * * *

Sec.

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§ 1.153 Submission of the Authority's annual reports, midyear reports, and strategic plans.

(a) *Annual financial report.* Every year, by May 15, the Authority must follow the procedures in § 1.143 to submit an annual financial report to the Commission, detailing the items listed in paragraphs (a)(1) through (9) of this section for the previous calendar year. The Authority must also publish this report on its website. The report must contain:

(1) A complete accounting of the Authority's budget, as audited by a qualified, independent, registered public accounting firm and in accordance with Generally Accepted Accounting Principles (including a statement from the auditor attesting to the auditor's independence and its opinion regarding the financial statements presented in the annual financial report);

(2) Line-item comparisons between the approved budget's revenues and expenditures for the previous year and the actual revenues and expenditures for the previous year;

(3) An explanation of how the Authority has considered the relative costs and benefits in formulating the programs, projects, and activities described in the budget;

(4) A description and accounting of the Authority's insurance coverage;

(5) A description and accounting of any budgetary reserves;

(6) Summaries of contracts or other liabilities that the Authority has entered into or may potentially incur;

(7) A summary of travel expenses, including an itemized list of any first-class travel (defined as the highest and most expensive class of service);

(8) Any new or continuing material or significant risks or issues raised by the audit, internal quality or control reviews, other inspections or peer reviews of the Authority, or any inquiry or investigation by governmental or professional authorities, along with any steps taken (*e.g.,* corrective actions) to deal with any such issues, consistent with § 1.154; and

(9) Any other information requested by Commission staff.

(b) *Annual performance report.* Every year, by March 31, the Authority must follow the procedures in § 1.143 to submit an annual performance report to the Commission, detailing the items listed in paragraphs (b)(1) through (11) of this section for the previous calendar year. The Authority must also publish this report on its website. The report must contain:

(1) Narrative summaries of all the major efforts by the Authority to carry out the requirements of the Act, including the status or results of any publicly announced investigations conducted by the Authority;

(2) Information about the Authority's cooperation with the States as set forth in 15 U.S.C. 3060(b), including whether each State has covered horseraces, elects to remit fees, or has entered into an agreement under 15 U.S.C. 3060(a)(1) to implement a component of the programs on racetrack safety or anti-doping and medication control;

(3) A summary of all final civil sanctions imposed by the Authority in the previous year, in a tabular format. At a minimum, the summary should be broken down by violation category (*e.g.,* racetrack safety program, anti-doping and controlled medication protocol rules, etc.) and should include the total number of alleged violations by category, the number of times the violations were admitted and resolved without adjudication, the number of times any violations were contested and adjudicated, the number of times any sanctions were imposed, the number of times that no sanctions were imposed, the number of civil sanction notices that needed to be reissued or corrected, the total fines imposed, the total amount of purses forfeited, and the number of times the sanctions were appealed to the Commission's Administrative Law Judge;

(4) An assessment of the Authority's progress in meeting or not meeting its performance measures contained in its strategic plan per paragraph (d) of this section;

(5) A statement from each Board of Directors committee summarizing its work in the previous year and all

recommendations each such committee has made to the Board;

(6) Information about any changes in the composition of the Authority's Board of Directors or standing committees;

(7) Information about the relationship between the Authority and the anti-doping and medication control enforcement agency, including how the enforcement agency is performing under its contract with the Authority and how many years remain under the contract;

(8) A summary of all litigation to which the Authority is a party, including actions commenced by the Authority under 15 U.S.C. 3054(j);

(9) A summary of all subpoenas issued by the Authority under 15 U.S.C. 3054(c);

(10) Descriptions of any areas in which the Authority believes that improvements to its operations are warranted, together with the Authority's plans to achieve those improvements. Forward-looking information should reflect known and anticipated risks, uncertainties, future events or conditions, and trends that could significantly affect the Authority's future financial position, condition, or operating performance, as well as Authority actions that have been planned or taken to address those challenges; and

(11) Any other information requested by Commission staff.

(c) *Midyear reporting.* Every year, by August 15, the Authority must follow the procedures in § 1.143 to furnish to the Commission a same-year midyear report covering January through June, to include:

(1) Spending and staffing levels for the quarter ending June 30, compared to the levels in the Commission-approved budget;

(2) A summary of travel expenses, including an itemized list of any first-class travel (defined as the highest and most expensive class of service);

(3) The status of outstanding and completed corrective actions; and

(4) Any other information requested by Commission staff.

(d) *Strategic plan.* The Authority must develop and maintain a multiyear strategic plan. The Authority must follow the procedures in § 1.143 to submit its first strategic plan to the Commission on or before October 15, 2024. The Authority must reevaluate the strategic plan no less frequently than every five years. The Authority's annual budget must align with, and link spending to, the strategic goals. The strategic plan must include items such as a description of its State-by-State relationships and a discussion of planned rulemaking activities. The Authority must:

(1) Post its draft strategic plan on its website for a public comment period of at least 14 days;

(2) Present its final strategic plan to the Commission, along with a summary of its responses to public comments; and

(3) Publish its final strategic plan on its website.

(e) *Further guidance on strategic plan.* The Authority's strategic plan should include forecasts of the Authority's industry environment and its priority initiatives for the current and subsequent years. The strategic plan should also consider the impact that program levels and changes in methods of program delivery, including advances in technology, could have on program operations and administration. The strategic plan should identify several strategic goals aligned with the Authority's mission statement. Each strategic goal should have accompanying objectives, strategies, and performance measures. As guiding principles, performance measures should:

(1) Be limited to the vital few and demonstrate results;

(2) Cover multiple priorities;

(3) Provide useful information for decision-making;

(4) Be clear, measurable, objective, and reliable; and

(5) Focus on core program activities and priorities.

§ 1.154 Enterprise risk management.

(a) *Guiding principles.* The Authority must effectively manage risk to prevent conflicts of interest, waste, fraud, embezzlement, and abuse. To manage risk, the Authority must align the enterprise risk-management process to the goals and objectives noted in the Authority's strategic plan. The Authority must assess risks, select risk responses, monitor whether responses are successful, and communicate and report on risks, consistent with § 1.153. The Authority must ensure that all internal controls have appropriate separation of duties (*e.g.,* requester, approver, recorder). In addition, the Authority must develop corrective action plans no later than 90 days after receiving a notice of finding from its auditors or other internal assessments. The Board of Directors (or one of the Authority's standing committees) must review and evaluate identified risks and proposed corrective action plans. The Authority must review regularly its corrective actions identified from all audits and internal assessments and should develop criteria by which to prioritize its response activities. The Authority must ensure that its risk management activities encompass:

(1) Compliance with applicable laws, rules, and regulations;

(2) The avoidance of conflicts of interest, or the appearance thereof, in all aspects of the Authority's operations, including investigation and enforcement, vendor selection, personnel assignments and responsibilities, and actions by the Board of Directors or management; and

(3) Handling funds received and expended by the Authority, including revenue/expense policies, fundraising practices, contracting policies, travel policies, and real and personal property agreements and expenses.

(b) *Data security and privacy.* The Authority must ensure the privacy and security of data, including all reasonable measures to protect the confidentiality of any sensitive health information (SHI), personally identifiable Information (PII), and sensitive PII (SPII) stored in its systems, including those operated by the anti-doping and medication control program, the Horseracing Integrity and Welfare Unit, and the Authority's third-party contractors. The Authority must ensure a complete annual evaluation of the status of its overall information technology security program and practices, as audited by a qualified, independent, third-party auditor. The Authority must also ensure that it has policies, programs, and practices in place to protect SHI, PII, and SPII. The Authority must send a copy of the annual evaluation to Commission staff.

(c) *Vendor selection.* Procurement actions estimated at over $10,000 must be accompanied by documented market research (*e.g.,* comparing the prices and other terms offered by the selected vendor against the prices and other terms offered by at least two other vendors) to ensure lowest cost or best value for goods or services to be provided. The Authority should also develop policies and procedures covering procurement activities.

(d) *Notice.* The Authority must provide advance notice to Commission staff of all significant Authority-planned events (*e.g.,* press conferences, media events, summits, etc.) via a calendar, a list, email, or some other reasonable means. The Authority must also summarize key aspects of all such events on its website within a reasonable timeframe. The Authority must also give Commission staff prompt notice after it has been alerted to significant, adverse events in the horseracing industry (*e.g.,* adverse safety

or medical events that might reasonably lead to sanctions, track closures, etc.).

§ 1.155 Other best practices.

(a) *Regular monitoring meetings.* The Commission recommends that the Authority hold regular meetings with Commission staff to discuss upcoming or potential risks, challenges, and opportunities for improvement.

(b) *Records and information management.* The Commission recommends that the Authority maintain records and information in sufficient detail to support the Authority's programs and operations, as well as any records relating to its information management policies or procedures. The Commission expects that the Authority will make any of these records available to Commission staff upon request, to allow the Commission to carry out its statutorily mandated oversight.

(c) *Treatment of confidential information.* The Commission recommends that the Authority's submissions to the Commission not include any SHI, PII, or SPII, such as a Social Security number; date of birth; driver's license number or other State identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. If the Authority submits documents to the Commission containing confidential commercial or financial information, it should so designate that material and request confidential treatment pursuant to § 4.10(g) of this chapter.

(d) *Standing data requests.* The Commission recommends that the Authority submit Board of Directors minutes to the Commission's Office of the Secretary within 30 days following each Board meeting.

(e) *Personnel and compensation.* The Commission recommends that the Authority develop compensation policies and practices with the primary objective of attracting, developing, and retaining high-performing individuals capable of achieving the Authority's mission. The Authority should strive to recruit a diverse team of industry leaders whose unique backgrounds, education, cultures, and perspectives help position the Authority as an effective and innovative self-regulatory organization. The Commission also recommends that the Authority conduct periodic salary benchmarks to ensure that employee compensation is in line with other like organizations.

(f) *Customer service.* The Commission recommends that the Authority maintain publicly accessible points of contact (*e.g.,* email addresses, phone numbers) and monitor the timeliness with which it responds to inquiries. In this regard, the Commission urges the Authority to develop a policy and associated metrics covering its customer service activities, to be incorporated into its strategic plan and its regular reporting to the Commission.

(g) *Travel.* The Commission recommends that the Authority use standard, General Services Administration (GSA)-established, published per diem rates when determining how much a person may spend on lodging, meals, and incidental expenses. Nevertheless, actual subsistence expenses may be authorized under unusual circumstances with justification and prior approval from the appropriate approving official. The Commission urges the Authority to prohibit the use of first-class travel (defined as the highest and most expensive class of service) by employees, except when no other option is available or when a disability or exceptional security conditions require it. The Commission also recommends that the Authority not reimburse its contractors for first-class travel unless exceptional circumstances warrant.

§ 1.156 Severability.

The provisions of this subpart are separate and severable from one another. If any provision is stayed or determined to be invalid, it is the Commission's intention that the remaining provisions shall continue in effect.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2024–18245 Filed 8–15–24; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2024–N–3655]

Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect and Identify Nucleic Acid Targets Including SARS–CoV–2 in Respiratory Specimens

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS–CoV–2 respiratory infection and other microbial agents when in a multi-target test into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS–CoV–2 respiratory infection and other microbial agents when in a multi-target test's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective August 16, 2024. The classification was applicable on March 17, 2021.

FOR FURTHER INFORMATION CONTACT: Uwe Scherf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3110, Silver Spring, MD 20993–0002, 301–796–5456, *Uwe.Scherf@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS–CoV–2 respiratory infection and other microbial agents when in a multi-target test as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).