Control(s)	Country chart (see Supp. No. 1 to part 738)
MT applies to ''technology'' for items controlled by 2B004, 2B009, 2B104, 2B105, 2B109, 2B116, 2B117, 2B119 to 2B122, 2D001, or 2D101 for MT reasons.	MT Column 1.
NP applies to ''technology'' for items controlled by 2A225, 2A226, 2B001, 2B004, 2B006, 2B007, 2B009, 2B104, 2B109, 2B116, 2B201, 2B204, 2B206, 2B207, 2B209, 2B225 to 2B233, 2D001, 2D002, 2D101, 2D201, or 2D202 for NP reasons.	NP Column 1.
NP applies to ''technology'' for items controlled by 2A290, 2A291, or 2D290 for NP reasons.	NP Column 2.
CB applies to ''technology'' for equipment controlled by 2B350 to 2B352, valves controlled by 2A226 having the characteristics of those controlled by 2B350.g, and software controlled by 2D351 or 2D352.	CB Column 2.
AT applies to entire entry.	AT Column 1.

Reporting Requirements

See § 743.1 of the EAR for reporting requirements for exports under License Exceptions, and Validated End-User authorizations.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: Yes, except N/A for MT

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit ''technology'' according to the General Technology Note for the ''development'' of ''software'' specified in the License Exception STA paragraph in the License Exception section of ECCN 2D001 or for the ''development'' of equipment as follows: ECCN 2B001 entire entry; or ''Numerically controlled'' or manual machine tools as specified in 2B003 to any of the destinations listed in Country Group A:6 (See Supplement No. 1 to part 740 of the EAR).

List of Items Controlled

Related Controls: See also 2E101, 2E201, and 2E301

Related Definitions: N/A

Items:

The list of items controlled is contained in the ECCN heading.

Note 1 to 2E001: ECCN 2E001 includes ''technology'' for the integration of probe systems into coordinate measurement machines specified by 2B006.a.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2021–21493 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–33–P

FEDERAL TRADE COMMISSION

16 CFR Part 1

Procedures for Submission of Rules Under the Horseracing Integrity and Safety Act

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') is issuing rules pursuant to the Horseracing Integrity and Safety Act (''Act'') to provide procedures for the Horseracing Integrity and Safety Authority (''Authority'') to submit its proposed rules and proposed rule modifications to the Commission for review.

DATES: These rule revisions are effective on October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Austin King (202–326–3166), Associate General Counsel for Rulemaking, 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, directs the Federal Trade Commission to oversee the activities of a private, self-regulatory organization called the Horseracing Integrity and Safety Authority.

Section 4(a) of the Act, 15 U.S.C. 3053(a), requires the Authority to submit to the Commission, in accordance with such rules as the Commission may prescribe under Section 553 of Title 5, United States Code, any proposed rule, or proposed modification to a rule, of the Authority relating to: (1) The bylaws of the Authority; (2) a list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods; (3) laboratory standards for accreditation and protocols; (4) standards for racing surface quality maintenance; (5) racetrack safety standards and protocols; (6) a program for injury and fatality data analysis; (7) a program of research and education on safety, performance, and anti-doping and medication control; (8) a description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons; (9) a schedule of civil sanctions for violations; (10) a process or procedures for disciplinary hearings; and (11) a formula or methodology for determining the assessments described in 15 U.S.C. 3052(f).

Accordingly, the Commission is adding a new subpart S to part 1 of its Rules of Practice, to provide procedures for the Authority to file its proposed rules and proposed modifications to existing rules with the Commission for review.

I. Section 1.140—Definitions

Section 1.140 defines relevant terms used in the proposed regulations. Each definition is based on a corresponding definition contained in Section 2 of the Act, 15 U.S.C. 3051, except as otherwise noted below.

The definition of ''HISA Guidance'' derives from Section 5(g)(1) of the Act, 15 U.S.C. 3054(g)(1), which states the Authority may issue guidance that ''sets forth an interpretation of an existing rule, standard, or procedure of the Authority'' or a ''policy or practice with respect to the administration or enforcement of such an existing rule, standard, or procedure'' and ''relates solely to the administration of the Authority; or any other matter, as specified by the Commission, by rule, consistent with the public interest and the purposes of this subsection [15 U.S.C. 3054(g)(1)].'' The Commission is adopting this definition and adding that HISA Guidance does not have the force of law, to distinguish HISA Guidance from a proposed modification to a rule.

The Act does not contain definitions for ''proposed rule'' or ''proposed modification.'' However, because these terms are used frequently throughout the regulations, the Commission is defining them for clarity. ''Proposed rule'' is defined as any rule proposed by the Authority pursuant to the Act. ''Proposed rule modification'' or ''modification'' is defined as any proposed modification to a rule, proposed rule change, or any interpretation or statement of policy or practice relating to an existing rule of the Authority that is not HISA Guidance and would have the force of law if

[1] 15 U.S.C. 3051 through 3060.

approved as a final rule. A proposed modification is distinguished from HISA Guidance in that a modification would have the force of law if approved and must therefore be approved by the Commission pursuant to Section 4(b)(2) of the Act, 15 U.S.C. 3053(b)(2). HISA Guidance need not be approved by the Commission but takes effect upon submission to the Commission pursuant to Section 5(g)(3) of the Act, 15 U.S.C. 3054(g)(3).

II. Section 1.141—Required Submissions

The Act requires the Authority to submit proposed rules or proposed rule modifications on certain subjects to the Commission for approval. These subjects are set forth in Section 4(a) of the Act, 15 U.S.C. 3053(a), which states the Authority must submit to the Commission, in accordance with such rules as the Commission may prescribe under Section 553 of Title 5, any proposed rule, or proposed modification to a rule, of the Authority relating to: (1) The bylaws of the Authority; (2) a list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods; (3) laboratory standards for accreditation and protocols; (4) standards for racing surface quality maintenance; (5) racetrack safety standards and protocols; (6) a program for injury and fatality data analysis; (7) a program of research and education on safety, performance, and anti-doping and medication control; (8) a description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons; (9) a schedule of civil sanctions for violations; (10) a process or procedures for disciplinary hearings; and (11) a formula or methodology for determining assessments described in 15 U.S.C. 3052(f). The Commission is adopting this language in its regulations.

The Commission is also adding a provision that the Authority must submit ''any other proposed rule or modification the Act requires the Authority to submit to the Commission for approval.'' For instance, the Act requires the Authority to submit rules regarding modifications to baseline anti-doping standards (15 U.S.C. 3055(g)(3)(b)) and modifications to racetrack safety rules (15 U.S.C. 3056(c)(2)(B)(ii)). Section 5(c)(2) of the Act, 15 U.S.C. 3054(c)(2), requires the Authority to submit to the Commission for approval any rules and procedures under Section 5(c)(1)(A) of the Act, 15 U.S.C. 3054(c)(1)(A), authorizing access to offices, racetrack facilities, other places of business, books, records, and personal property of covered persons used in the care, treatment, training, and racing of covered horses; authorizing the issuance and enforcement of subpoenas and subpoenas duces tecum; and authorizing other investigatory powers of the nature and scope exercised by State racing commissions before the program effective date. Such proposed rules and modifications must also be submitted to the Commission for approval.

III. Section 1.142—Submission of Proposed Rule or Modification

The Act requires the Commission to evaluate the Authority's proposed rules and modifications to determine whether they are consistent with the Act and the applicable rules approved by the Commission. *See* 15 U.S.C. 3053(c)(2). To avoid delays in the rule review process, the Commission is requiring the Authority to submit the information necessary for it to evaluate the proposed rule or modification promptly and efficiently. Section 1.142 is designed to elicit the information the Commission needs to determine whether the proposed rule or modification is consistent with the Act and the rules and regulations issued thereunder.

A. Contents of Submission

For a submission to qualify as a proposed rule or proposed modification to a rule under Section 4(a) of the Act, 15 U.S.C. 3053(a), the Authority must submit a complete draft of the **Federal Register** document for its proposed or modified rule, which includes the text of the rule and a statement of the purpose of, and statutory basis for, the proposed rule or modification. The Commission's intention is to require the Authority to provide an explanation of its rules that will allow both the Commission and the public to understand the nature and purpose of its proposed rules or modifications—the reasons for adopting the proposed rule or modification; any problems the proposed rule or modification is intended to address and how the proposed rule or modification will resolve those problems; and how the proposed rule or modification will affect covered persons, covered horses, and covered horseraces.

The Commission is also requiring the Authority to explain the statutory basis for its proposed rules or modifications. To evaluate a proposed rule or modification, the Commission must be able to understand why the Authority believes its proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission. Evaluation of a proposed rule or modification will also be aided by the Authority's description of any reasonable alternatives it considered and the reasons it selected the proposed rule or modification over the alternatives.

The Act does not give the Authority broad discretion in developing rules. It sets forth guardrails, in the form of baseline standards for anti-doping and medication control (15 U.S.C. 3055(g)(2)(A)), racetrack safety standards which the Authority must consider (15 U.S.C. 3056(a)(2)), guidelines for determining funding and calculating costs (15 U.S.C. 3052(f)(1)(C)(ii)), a specific formula for the assessment and collection of fees (15 U.S.C. 3052(f)(3)(C)), who must register with the Authority and the conditions of registration (15 U.S.C. 3054(d)), guidelines for establishing rule violations (15 U.S.C. 3057(a)(2)), requisite elements of the Authority's results management and disciplinary program (15 U.S.C. 3057(c)(2)), guidelines for establishing civil sanctions (15 U.S.C. 3057(d)(2)), and more. Accordingly, the Authority must explain why its proposed rule or modification is consistent with any standards in the Act and the rules approved by the Commission. Because the requisite considerations for anti-doping and racetrack safety are the most prescriptive, this section specifically addresses those standards and factors. The less prescriptive standards and factors must also be addressed, and the Commission provides for this in a less prescriptive rule, as discussed below.

1. Anti-Doping and Medication Control Program Considerations

When proposing a rule or modification to the horseracing anti-doping and medication control program, the Authority must explain how it considered the factors in Section 6 of the Act, 15 U.S.C. 3055, including the unique characteristics of a breed of horse made subject to the Act by election of a State racing commission or breed governing organization for such horse pursuant to Section 5(*l*) of the Act, 15 U.S.C. 3054(*l*), as required by Section 6(a)(2) of the Act, 15 U.S.C. 3055(a)(2). The Authority must explain how it considered the factors in Section 6(b) of the Act, 15 U.S.C. 3055(b), namely that: (1) Covered horses should compete only when they are free from the influence of medications, other foreign substances, and methods that affect their performance; (2) covered horses that are injured or unsound should not train or participate in covered races, and the use

of medications, other foreign substances, and treatment methods that mask or deaden pain in order to allow injured or unsound horses to train or race should be prohibited; (3) rules, standards, procedures, and protocols regulating medication and treatment methods for covered horses and covered races should be uniform and uniformly administered nationally; (4) to the extent consistent with chapter 57A of title 15, consideration should be given to international anti-doping and medication control standards of the International Federation of Horseracing Authorities and the Principles of Veterinary Medical Ethics of the American Veterinary Medical Association; (5) the administration of medications and treatment methods to covered horses should be based on an examination and diagnosis that identifies an issue requiring treatment for which the medication or method represents an appropriate component of treatment; (6) the amount of therapeutic medication a covered horse receives should be the minimum necessary to address the diagnosed health concerns identified during the examination and diagnostic process; and (7) the welfare of covered horses, the integrity of the sport, and the confidence of the betting public require full disclosure to regulatory authorities regarding the administration of medications and treatments to covered horses.

In addition, Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A), provides that certain baseline anti-doping and medication control rules must constitute the initial rules of the horseracing anti-doping and medication control program and, except as exempted pursuant to Section 6(e) and (f) of the Act, 15 U.S.C. 3055(e) and (f), remain in effect at all times after the program effective date. Such baseline anti-doping and medication control rules include: (1) The lists of permitted and prohibited substances (including drugs, medications, and naturally occurring substances and synthetically occurring substances) in effect for the International Federation of Horseracing Authorities, including the International Federation of Horseracing Authorities International Screening Limits for urine, dated May 2019, and the International Federation of Horseracing Authorities International Screening Limits for plasma, dated May 2019; (2) the World Anti-Doping Agency International Standard for Laboratories (version 10.0), dated November 12, 2019; (3) the Association of Racing Commissioners International out-of-competition testing standards, Model Rules of Racing (version 9.2); and (4) the Association of Racing Commissioners International penalty and multiple medication violation rules, Model Rules of Racing (version 6.2). In the case of a conflict among the rules, Section 6(g)(2)(B) of the Act, 15 U.S.C. 3055(g)(2)(B), provides that the most stringent rule shall apply. Accordingly, the Commission is requiring the Authority to state whether a proposed rule adopts the baseline standards identified in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A). If there is a conflict in any baseline standards identified in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A), the Authority must identify the conflict and state whether the standard it adopted is the most stringent standard. Under Section 6(g)(3)(C) of the Act, 15 U.S.C. 3055(g)(3)(C), ''[t]he Authority shall not approve any proposed modification that renders an anti-doping and medication control rule less stringent than the baseline anti-doping and medication control rules . . . without the approval of the anti-doping and medication control enforcement agency.'' Thus, for a proposed rule modification, the Authority must explain whether the modification renders an anti-doping and medication control rule less stringent than the baseline anti-doping and medication control rules described in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A), and state whether the anti-doping and medication control enforcement agency has approved of the change.

2. Racetrack Safety Program Considerations

Section 7 of the Act, 15 U.S.C. 3056, requires the Authority to consider certain factors when developing the racetrack safety program. Accordingly, when proposing a rule or modification to any rule regarding its racetrack safety program, the Authority must explain how the proposed rule or modification meets the requirements in Section 7(b) of the Act, 15 U.S.C. 3056(b), which provides that the horseracing safety program must include the following: (1) A set of training and racing safety standards and protocols taking into account regional differences and the character of differing racing facilities; (2) a uniform set of training and racing safety standards and protocols consistent with the humane treatment of covered horses, which may include lists of permitted and prohibited practices or methods (such as crop use); (3) a racing surface quality maintenance system that takes into account regional differences and the character of differing racing facilities (which may include requirements for track surface design and consistency and established standard operating procedures related to track surface, monitoring, and maintenance, such as standardized seasonal assessment, daily tracking, and measurement); (4) a uniform set of track safety standards and protocols, that may include rules governing oversight and movement of covered horses and human and equine injury reporting and prevention; (5) programs for injury and fatality data analysis, that may include pre- and post-training and race inspections, use of a veterinarian's list, and concussion protocols; (6) the undertaking of investigations at racetrack and non-racetrack facilities related to safety violations; (7) procedures for investigating, charging, and adjudicating violations and for the enforcement of civil sanctions for violations; (8) a schedule of civil sanctions for violations; (9) disciplinary hearings, which may include binding arbitration, civil sanctions, and research; (10) management of violation results; (11) programs relating to safety and performance research and education; and (12) an evaluation and accreditation program that ensures racetracks in the United States meet the standards described in the elements of the Horseracing Safety Program.

The Authority must also consider the safety standards in Section 7(a)(2) of the Act, 15 U.S.C. 3056(a)(2), which provide that in the development of the horseracing safety program for covered horses, covered persons, and covered horseraces, the Authority and the Commission must take into consideration existing safety standards, including the National Thoroughbred Racing Association Safety and Integrity Alliance Code of Standards, the International Federation of Horseracing Authority's International Agreement on Breeding, Racing, and Wagering, and the British Horseracing Authority's Equine Health and Welfare program. The Commission is therefore requiring the Authority to explain how it considered and whether it adopted any of the standards in Section 7(a)(2) of the Act,15 U.S.C. 3056(a)(2). If any horseracing safety standards in Section 7(a)(2) of the Act, 15 U.S.C. 3056(a)(2), were considered but not adopted or were modified, the Authority must explain why it decided not to adopt or why it decided to modify such standard.

3. Other Considerations

The Commission is incorporating the specific anti-doping and racetrack safety standards into this section because they are the most prescriptive and extensive, but this should not be read as an

invitation to dispense with the less-prescriptive guardrails set forth in the Act. To the extent the Act requires the Authority to consider any factors or standards not specifically referenced in this section, the Authority must explain whether and how it considered those factors when proposing a rule or modification. For instance, when proposing a civil sanctions rule or modification pursuant to Section 8(d)(1) of the Act, 15 U.S.C. 3057(d)(1), the Authority must explain how the rule or modification meets the requirements of Section 8(d)(2) of the Act, 15 U.S.C. 3057(d)(2).

B. Supporting Documentation

The Commission is requiring the Authority to submit any pertinent factual information it relied on in developing its proposed rule or modification. More specifically, the Authority's submission to the Commission must include a copy of existing standards used as a reference for the development of a proposed rule or modification and any scientific data, studies, or analysis underlying the development of the proposed rule or modification. The Commission anticipates receiving, for instance, a copy of the lists of permitted and prohibited substances in effect for the International Federation of Horseracing Authorities, including the International Federation of Horseracing Authorities International Screening Limits for urine, dated May 2019, and any other rules and standards referenced in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A) when the Authority's baseline rules for anti-doping are submitted. For organizational purposes, supporting documentation must be attached as exhibits, and each exhibit must clearly identify the proposed rule or modification it supports.

C. Redline Document for Proposed Rule Modification

To enable the Commission to quickly and easily identify the substance of a proposed rule modification, the Commission is requiring the Authority to provide a redline document of the existing rule, marked with the proposed changes.

D. Timing of Submission

Section 4(c)(1) of the Act, 15 U.S.C. 3053(c)(1) provides for a 60-day timeframe between the Commission's publication of the Authority's proposed rule or modification in the **Federal Register** for public comment and the date the Commission must approve or disapprove the Authority's proposed rule or modification. To ensure it has sufficient time for review, the Commission is requiring the Authority to provide the information it needs to evaluate the Authority's proposed rule or modification at least 90 days in advance of the date the Authority proposes having its proposed rule or modification published in the **Federal Register** for public comment. This will give the Commission additional time to evaluate the Authority's proposed rule or modification. It should be noted this 90-day timeframe serves as a minimum, not a maximum, timeframe. The Secretary may shorten the timeframe if the Authority demonstrates that a shorter timeframe is necessary to meet statutory deadlines.

E. Conclusory Statements and Failure To Provide Requisite Analysis

The Authority must provide an adequate basis for the Commission's review of its rules. The Commission seeks to understand the Authority's analysis of the information it relied on to determine whether a proposed rule or modification was warranted and if so, what provisions the rule should contain. To this end, the information required under this section must be sufficiently detailed and contain sufficient analysis to support a Commission finding that a proposed rule or modification satisfies the statutory requirements. A mere assertion or conclusory statement that a proposed rule or modification is consistent with the requirements of the Act, for instance, is insufficient. If the Authority fails to describe and justify the proposed rule or modification in the manner described in this section, or fails to submit the information required by this section, the Commission may not have sufficient information to make an affirmative finding that the proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission.

F. Public Comments

Section 4(d)(2) of the Act, 15 U.S.C. 3053(d)(2), provides the ''Commission shall publish in the **Federal Register** any [ ] proposed rule, standard, or procedure and provide an opportunity for public comment.'' However, the Act gives the Commission only a total of 60 days after publication to approve or disapprove a proposed rule or modification once it has been published in the **Federal Register**. Given that the Commission and the Authority will need time to review comments, the Act functionally provides for a much more limited comment period of approximately 30 days or less. To ensure the public has an adequate opportunity to review and understand the Authority's rules, ask questions, and provide comments, the Commission is encouraging the Authority to make its proposed rules publicly available and solicit public comments in advance of providing any submissions to the Commission. To avoid delays in Commission approval of its rules, the Authority should not wait until its proposed rule is published in the **Federal Register** to solicit its own public comments.

In a March 21, 2021 letter [2] to the Acting Chairwoman, Rebecca Kelly Slaughter, the Act's sponsors stated ''[t]he relationship between the [Commission] and the Authority is closely modeled on the enduring and effective relationship between the Securities and Exchange Commission (SEC) and Financial Industry Regulatory Authority (FINRA), a private self-regulatory organization.'' As part of its own rulemaking process, the FINRA Board of Governors may authorize the publication of its own Regulatory Notice soliciting comments on a rule proposal prior to its submission to the SEC.[3] If FINRA decides to issue a Regulatory Notice soliciting public comment on a proposal, the comment period typically is open for one to two months.[4] All comments become part of FINRA's ''official record'' of the rule proposal, and since December 1, 2003, FINRA has posted all comment letters on its website.[5] Depending on the comments received in response to the Regulatory Notice and any changes made to the proposal, FINRA staff will either return to the FINRA Board with a revised proposal or will file the rule proposal with the SEC for notice and comment.[6] Soliciting comments, as FINRA does, in advance of submitting any proposed rules or modifications to the Commission would benefit both the Authority, the regulated community, and the Commission. It would provide transparency and enable the Authority to resolve any issues with its rules prior to their submission to the Commission.

If public comments are solicited, the Commission is requiring the Authority to attach, as an exhibit to its submission under § 1.142, a copy of the comments. The Commission encourages the Authority to make such comments publicly available on its own website. In

[2] *See* Letter from Senator Mitch McConnell to Acting Chairwoman Rebecca Kelly Slaughter (Mar. 23, 2021) (on file with the Federal Trade Commission).

[3] *See* FINRA Rulemaking process, *https://www.finra.org/rules-guidance/rulemaking-process* (last visited July 9, 2021).

[4] *Id.*

[5] *Id.*

[6] *Id.*

addition, the Authority's draft **Federal Register** document must include a summary of the substance of all comments received and the Authority's written response to all significant issues raised in such comments. This advance resolution of comments will greatly facilitate the process of review of any proposed rules or modifications the Authority submits to the Commission.

IV. Section 1.143—Submissions to the Secretary

This section provides guidance for the Authority when submitting documents to the Secretary of the Commission.

All rule submissions made pursuant to § 1.142 and 15 U.S.C. 3053(a), rate increases which must be reported to the Commission under 15 U.S.C. 3052(f)(1)(C)(iv), or HISA Guidance which must be submitted to the Commission under 15 U.S.C. 3054(g)(2), must be emailed to the Secretary of the Commission at *electronicfilings@ftc.gov*. The subject line of the email must state: ''HISA Rule Submission,'' ''HISA Rate Increase Submission,'' or ''HISA Guidance Submission'' as applicable. This will enable the Secretary to easily identify submissions from the Authority and route them to the appropriate office.

To facilitate Commission review, documents must be organized and sent in a format that will facilitate the submission of documents to the Office of the Federal Register. Except for supporting documentation submitted pursuant to § 1.142(b) (existing standards used as a reference for the development of the proposed rule or modification, and scientific data, studies, or analysis underlying the development of the proposed rule or modification) and copies of public comments submitted pursuant to § 1.142(f), all documents submitted to the Secretary must be in a word processing format. This will enable the Commission to more easily make modifications to **Federal Register** documents, provide feedback on rule text, and draft orders. For organizational purposes, the Commission is requiring submissions with more than one attachment to contain a table of contents in the body of the email with a brief description of each item. The Authority must also provide the contact information for a person on the staff of the Authority responsible for responding to questions from the Commission. To facilitate submissions to the Office of the Federal Register, the Commission is requiring that the Authority's draft **Federal Register** documents follow the relevant format and editorial requirements for regulatory documents in the Office of **Federal Register**'s Document Drafting Handbook, 1 CFR parts 18, 21, and 22. Specifically, draft **Federal Register** documents must contain proper preamble captions and content; state the purpose of, and basis for, the proposed rule or modification; set forth regulatory text, headings, and authority citations; use correct numbering, structure, and amendatory language; and conform to style and formatting established by the Office of the Federal Register and Government Publishing Office (see, specifically, section 2.17 (proposed rules) of the Office of the Federal Register's Document Drafting Handbook).

If a document filed with the Secretary contains confidential information, the Secretary must be so informed, and a request for confidential treatment must be submitted in accordance with 16 CFR 4.9. Filings submitted electronically on or before 5:30 p.m. Eastern Time, on a business day, will be deemed filed on that business day, and all filings submitted after 5:30 p.m. Eastern Time, will be deemed filed on the next business day. This section also provides the Secretary of the Commission may reject a document for filing that fails to comply with the Commission's rules for filing in this section or § 1.142. Finally, if the conditions in this section and § 1.142 have been satisfied, the Commission will publish the proposed rules or modifications in the **Federal Register** for public comment.

V. Section 1.144—Approval or Disapproval of Proposed Rules or Modifications

Section 4(c)(1) of the Act, 15 U.S.C. 3053(c)(1) provides, ''Not later than 60 days after the date on which a proposed rule or modification is published in the **Federal Register**, the Commission shall approve or disapprove the proposed rule or modification.'' In addition, Section 4(c)(2) of the Act, 15 U.S.C. 3053(c)(2), provides ''[t]he Commission shall approve a proposed rule or modification if the Commission finds that the proposed rule or modification is consistent with [ ] this chapter; and [ ] applicable rules approved by the Commission.'' Accordingly, § 1.144 provides the Commission will approve or disapprove a proposed rule or modification by issuing an order within 60 days of the date the proposed rule or modification was published in the **Federal Register** for public comment. The Commission will approve a proposed rule or modification if it finds such proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission. Further, a proposed rule or modification will not take effect unless it has been approved by the Commission.

Because these rule revisions 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).[7]

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.

■ 2. Add subpart S to read as follows:

Subpart S—Procedures for Submissions Under the Horseracing Integrity and Safety Act

Sec.

Authority: 15 U.S.C. 3053.

§ 1.140 Definitions.

When used in relation to the Horseracing Integrity and Safety Act, 15 U.S.C. 3051 through 3060, and this subpart—

Act means the Horseracing Integrity and Safety Act, 15 U.S.C. 3051 through 3060.

Breeder means a person who is in the business of breeding covered horses.

Commission means the Federal Trade Commission.

Covered horse means any Thoroughbred horse, or any other horse made subject to the Act by election of the applicable State racing commission or the breed governing organization for such horse under 15 U.S.C. 3054(*l*), during the period—

(1) Beginning on the date of the horse's first timed and reported workout at a racetrack that participates in covered horseraces or at a training facility; and

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

(2) Ending on the date on which the Authority receives written notice that the horse has been retired.

Covered horserace means any horserace involving covered horses that has a substantial relation to interstate commerce, including any Thoroughbred horserace that is the subject of interstate off-track or advance deposit wagers.

Covered persons means all trainers, owners, breeders, jockeys, racetracks, veterinarians, persons (legal and natural) licensed by a State racing commission and the agents, assigns, and employees of such persons and other horse support personnel who are engaged in the care, training, or racing of covered horses.

HISA Guidance means Horseracing Integrity and Safety Authority (Authority) guidance issued under 15 U.S.C. 3054(g)(1), which does not have the force of law.

Horseracing anti-doping and medication control program means the anti-doping and medication program established under 15 U.S.C. 3055(a).

Horseracing Integrity and Safety Authority or *Authority* means the private, independent, self-regulatory, nonprofit corporation recognized for purposes of developing and implementing a horseracing anti-doping and medication control program and a racetrack safety program for covered horses, covered persons, and covered horseraces.

Interstate off-track wager has the meaning given such term in Section 3 of the Interstate Horseracing Act of 1978, 15 U.S.C. 3002.

Jockey means a rider or driver of a covered horse in covered horseraces.

Owner means a person who holds an ownership interest in one or more covered horses.

Proposed rule means any rule proposed by the Authority pursuant to the Act.

Proposed rule modification or *modification* means:

(1) Any proposed modification to a rule or proposed rule change; or

(2) Any interpretation or statement of policy or practice relating to an existing rule of the Authority that is not HISA Guidance and would have the force of law if approved as a final rule.

Racetrack means an organization licensed by a State racing commission to conduct covered horseraces.

Racetrack safety program means the program established under 15 U.S.C. 3056(a).

State racing commission means an entity designated by State law or regulation that has jurisdiction over the conduct of horseracing within the applicable State.

Trainer means an individual engaged in the training of covered horses.

Training facility means a location that is not a racetrack licensed by a State racing commission that operates primarily to house covered horses and conduct official timed workouts.

Veterinarian means a licensed veterinarian who provides veterinary services to covered horses.

Workout means a timed running of a horse over a predetermined distance not associated with a race or its first qualifying race, if such race is made subject to the Act by election under 15 U.S.C. 3054(*l*) of the horse's breed governing organization or the applicable State racing commission.

§ 1.141 Required submissions.

The Authority must submit to the Commission any proposed rule, or proposed rule modification, of the Authority relating to—

(a) The bylaws of the Authority;

(b) A list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods;

(c) Laboratory standards for accreditation and protocols;

(d) Standards for racing surface quality maintenance;

(e) Racetrack safety standards and protocols;

(f) A program for injury and fatality data analysis;

(g) A program of research and education on safety, performance, and anti-doping and medication control;

(h) A description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons;

(i) A schedule of civil sanctions for violations;

(j) A process or procedures for disciplinary hearings;

(k) A formula or methodology for determining assessments described in 15 U.S.C. 3052(f); and

(l) Any other proposed rule or modification the Act requires the Authority to submit to the Commission for approval.

§ 1.142 Submission of proposed rule or modification.

(a) *Contents of submission.* In order for a submission to qualify as a proposed rule or proposed rule modification under 15 U.S.C. 3053(a), the Authority must submit to the Commission a complete draft of the **Federal Register** document for the proposed rule or proposed rule modification, which includes the text of the rule and a statement of the purpose of, and statutory basis for, the proposed rule or modification (''statement of basis and purpose''). The statement of basis and purpose must contain:

(1) The reasons for adopting the proposed rule or modification.

(2) Any problems the proposed rule or modification is intended to address and how the proposed rule or modification will resolve those problems.

(3) A description of any reasonable alternatives to the proposed rule or modification that may accomplish the stated objective and an explanation of the reasons the Authority chose the proposed rule or modification over its alternatives.

(4) How the proposed rule or modification will affect covered persons, covered horses, and covered horseraces.

(5) Why the proposed rule or modification is consistent with the requirements of the Act and any rules and regulations applicable to the Authority, including the following:

(i) *Anti-doping and medication control program.* When proposing a rule or modification to the horseracing anti-doping and medication control program, the Authority must explain how it considered the factors in 15 U.S.C. 3055, including:

(A) Under 15 U.S.C. 3055(a)(2), the unique characteristics of a breed of horse made subject to the Act by election of a State racing commission or breed governing organization for such horse pursuant to 15 U.S.C. 3054(*l*);

(B) The factors listed in 15 U.S.C. 3055(b); and

(C) The baseline anti-doping and medication control rules identified in 15 U.S.C. 3055(g)(2)(A). For a proposed rule, the Authority must state whether its proposed rule adopts the baseline standards identified in 15 U.S.C. 3055(g)(2)(A). If there is a conflict in any baseline standards identified in 15 U.S.C. 3055(g)(2)(A), the Authority must identify the conflict and state whether the standard it adopted is the most stringent standard. For a proposed rule modification, the Authority must explain whether the modification renders an anti-doping and medication control rule less stringent than the baseline anti-doping and medication control rules described in 15 U.S.C. 3055(g)(2)(A), and state whether the anti-doping and medication control enforcement agency has approved of the change.

(ii) *Racetrack safety program.* When proposing a rule or modification to any rule regarding the racetrack safety program required under 15 U.S.C. 3056(a)(1), the Authority must explain how the proposed rule or modification

meets the requirements in 15 U.S.C. 3056(b). The Authority must explain how it considered and whether it adopted the safety standards in 15 U.S.C. 3056(a)(2). If any horseracing safety standards in 15 U.S.C. 3056(a)(2) were considered but not adopted or were modified, the Authority must explain why it decided not to adopt or why it decided to modify such standard.

(iii) *Other rules.* To the extent the Act requires the Authority to consider any factors or standards not specifically referenced in this section, the Authority must explain whether and how it considered those factors when proposing a rule or modification. For instance, when proposing a civil sanctions rule or modification pursuant to 15 U.S.C. 3057(d)(1), the Authority must explain how the rule or modification meets the requirements of 15 U.S.C. 3057(d)(2).

(6) If written comments were solicited, the Authority's draft **Federal Register** document must include a summary of the substance of all comments received and the Authority's written response to all significant issues raised in such comments.

(7) The date that the Authority proposes for the **Federal Register** to publish its proposed rule or modification.

(b) *Supporting documentation.* The Authority's submission to the Commission required under paragraph (a) of this section must also include copies of the pertinent factual information underlying the Authority's development of the proposed rule or modification, including a copy of existing standards used as a reference for the development of the proposed rule or modification and scientific data, studies, or analysis underlying the development of the proposed rule or modification. Supporting documentation must be attached as exhibits, and each exhibit must clearly identify the proposed rule or modification it supports.

(c) *Redline document for proposed rule modification.* For proposed rule modifications, the Authority must also provide, in a document separate from the **Federal Register** document, a redline version of the existing rule that will enable the Commission to immediately identify any proposed changes.

(d) *Timing of submission.* To qualify as a proposed rule or proposed modification under 15 U.S.C. 3053(a), the Authority's submission must provide the information in paragraphs (a), (b), and (c) of this section at least 90 days in advance of the proposed date for the **Federal Register** to publish a proposed rule or modification for public comment pursuant to 15 U.S.C. 3053(b)(1). The Secretary may waive the 90-day requirement in this section if the Authority demonstrates such waiver is necessary to meet statutory deadlines.

(e) *Conclusory statements and failure to provide requisite analysis.* Information required to be submitted under this section must be sufficiently detailed and contain sufficient analysis to support a Commission finding that a proposed rule or modification satisfies the statutory requirements. For instance, a mere assertion or conclusory statement that a proposed rule or modification is consistent with the requirements of the Act is insufficient. Failure to describe and justify the proposed rule or modification in the manner described in this section or failure to submit the information required by this section may result in the Commission's having insufficient information to make an affirmative finding that the proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission.

(f) *Public comments.* The Authority is encouraged to solicit public comments on its proposed rule or modification in advance of making a submission to the Commission pursuant to this section. If the Authority solicits public comments, it must attach a copy of the comments as an exhibit to its submission. By soliciting public comments and addressing significant issues raised therein, the Authority facilitates the Commission's review and approval of the Authority's proposed rule or modification.

§ 1.143 Submissions to the Secretary.

(a) *Electronic submission.* All rule submissions under § 1.142 and 15 U.S.C. 3053(a), rate increases that must be reported to the Commission under 15 U.S.C. 3052(f)(1)(C)(iv), or HISA Guidance that must be submitted to the Commission under 15 U.S.C. 3054(g)(2) must be emailed to the Secretary of the Commission at *electronicfilings@ftc.gov*. The subject line of the email must state: ''HISA Rule Submission,'' ''HISA Rate Increase Submission,'' or ''HISA Guidance Submission,'' as applicable.

(b) *Format for submission of proposed rules or modifications*—(1) *Electronic format.* Except for supporting documentation submitted pursuant to § 1.142(b) and copies of comments submitted pursuant to § 1.142(f), all documents submitted to the Secretary must be in a word processing format.

(2) *Table of contents.* Submissions with more than one attachment must contain a table of contents in the body of the email with a brief description of each item.

(3) *Contact information.* The Authority must provide the name, telephone number, and email address of a person on the staff of the Authority responsible for responding to questions and comments on the submission in the body of the email.

(4) *Draft* ***Federal Register*** *documents.* Draft **Federal Register** documents must follow the relevant format and editorial requirements for regulatory documents under 1 CFR parts 18, 21, and 22 (see Office of Federal Register's Document Drafting Handbook). The Document Drafting Handbook specifies that draft **Federal Register** documents (see 1 CFR 15.10) must:

(i) Contain proper preamble captions and content;

(ii) State the purpose of, and basis for, the proposed rule or modification;

(iii) Set forth regulatory text, headings, and authority citations;

(iv) Use correct numbering, structure, and amendatory language; and

(v) Conform to the style and formatting established by the Office of the Federal Register and Government Publishing Office. (See, specifically, section 2.17 (proposed rules) of the Office of the Federal Register's Document Drafting Handbook.)

(c) *Confidential information.* If a document filed with the Secretary contains confidential information, the Secretary must be so informed, and a request for confidential treatment must be submitted in accordance with 16 CFR 4.9.

(d) *Date of filing.* If the conditions of this section are otherwise satisfied, all filings submitted electronically on or before 5:30 p.m. Eastern Time, on a business day, will be deemed filed on that business day, and all filings submitted after 5:30 p.m. Eastern Time, will be deemed filed on the next business day.

(e) *Authority to reject documents for filing.* The Secretary of the Commission may reject a document for filing that fails to comply with the Commission's rules for filing in this section or § 1.142.

(f) ***Federal Register*** *publication.* If the conditions in this section and § 1.142 have been satisfied, the Commission will publish the proposed rules or modifications in the **Federal Register** and request public comment on those proposed rules or modifications.

§ 1.144 Approval or disapproval of proposed rules and proposed rule modifications.

(a) *Commission decision.* The Commission will approve or disapprove

a proposed rule or modification by issuing an order within 60 days of the date the proposed rule or modification was published in the **Federal Register** for public comment.

(b) *Standard of review.* The Commission will approve a proposed rule or modification if the Commission finds that the proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission. If the Commission disapproves a rule or modification, it will make recommendations to the Authority to modify the proposed rule or modification within 30 days of such disapproval.

(c) *Effect.* A proposed rule or modification will not take effect unless it has been approved by the Commission.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2021–21306 Filed 10–4–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA–2018–N–0236]

RIN 0910–AH53

Medical Device De Novo Classification Process

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to establish requirements for the medical device De Novo classification process under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This final rule establishes procedures and criteria related to requests for De Novo classification (''De Novo request'') and provides a pathway to obtain marketing authorization as a class I or class II device and for certain combination products. These requirements are intended to ensure the most appropriate classification of devices consistent with the protection of the public health and the statutory scheme for device regulation. They are also intended to limit the unnecessary expenditure of FDA and industry resources that may occur if devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness are subject to premarket approval. The final rule implements the De Novo classification process under the FD&C Act, as enacted by the Food and Drug Administration Modernization Act of 1997 (FDAMA) and modified by the Food and Drug Administration Safety and Innovation Act (FDASIA) and the 21st Century Cures Act (Cures Act).

DATES: This rule is effective January 3, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Sergio de del Castillo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2431, Silver Spring, MD 20993, 301–796–6419.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

This rule establishes new regulations implementing the medical device De Novo classification process under the FD&C Act, which provides a pathway for certain new types of devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as a class III device, which would require premarket approval under the postamendments device classification section of the FD&C Act.

The De Novo classification process is intended to provide an efficient pathway to ensure the most appropriate classification of a device consistent with the protection of the public health and the statutory scheme for device regulation. When FDA classifies a device type as class I or II via the De Novo classification process, other manufacturers do not necessarily have to submit a De Novo request or premarket approval application (PMA) to legally market a device of the same type. Instead, manufacturers can use the less burdensome pathway of premarket notification (510(k)), when applicable, to legally market their device, because the device that was the subject of the original De Novo request can serve as a predicate device for a substantial equivalence determination.

B. Summary of the Major Provisions of the Final Rule

This rule establishes procedures and criteria for the submission and withdrawal of a De Novo request. It also establishes procedures and criteria for FDA to accept, review, grant, and/or decline a De Novo request. While several comments object to sections or subsections of the proposed rule, almost all comments voice support for the objective of the proposed rule: To establish regulations implementing the De Novo classification process. The rule provides that:

- A person may submit a De Novo request after submitting a 510(k) and receiving a not substantially equivalent (NSE) determination.
- A person may also submit a De Novo request without first submitting a 510(k), if the person determines that