



FEDERAL TRADE COMMISSION

[File No. P222100]

Horseracing Integrity and Safety Authority Anti-Doping and Medication Control

Rule Modification

AGENCY: Federal Trade Commission

ACTION: Notice of Horseracing Integrity and Safety Authority (HISA) proposed rule modification; request for public comment.

SUMMARY: As required by the Horseracing Integrity and Safety Act of 2020, the Federal Trade Commission (“FTC” or “Commission”) publishes a proposed rule modification related to the equine Anti-Doping and Medication Control Program of the Horseracing Integrity and Safety Authority (“HISA” or the “Authority”). Specifically, the proposed rule modification would designate iron dextran as a banned substance and thereby prohibit its use. This publication contains the Authority’s proposed rule’s text and explanation, and it seeks public comment on whether the Commission should approve the proposed rule.

DATES: The Commission must approve or disapprove the proposed modification on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. If approved, the proposed rule modification would be effective immediately. Comments must be filed on or before [INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY**

INFORMATION section. Write “HISA Anti-Doping and Medication Control Rule Modification” on your comment and file your comment online at

<https://www.regulations.gov> by following the instructions on the web-based form. If you

prefer to file your comment on paper, mail your comment to the following address:

Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex H), Washington, DC 20580.

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

SUPPLEMENTARY INFORMATION: On July 8, 2023, pursuant to section 3053(a) of the Horseracing Integrity and Safety Act of 2020 (“Act”)¹ and FTC Rule 1.142,² the Horseracing Integrity and Safety Authority (“HISA” or the “Authority”) filed with the Commission a proposed modification of the Authority’s anti-doping rules to include iron dextran as a banned substance. Sections I and II below set forth the Authority’s proposal. The Commission is publishing this document to solicit comments on the proposed rule modification from interested persons.

The proposed modification would insert the following row for Iron Dextran into the “Technical Document – Prohibited Substances” appendix to the Prohibited List (Rule Series 4000), between the row for Irbesartan and the row for Isoaminile.

¹ 15 U.S.C. 3051 through 3060.

² 16 CFR 1.142.

HISA listed as	HISA status	Penalty subclassification (Specified Substances are designated with 'x')	Substance	Action	Commercial name(s) (<i>developmental names</i>)	Detection Time	Screening Limit (unless Otherwise designated as a Threshold). Where no value is Listed for serum or plasma the substance

BANNED *****	S6		Iron Dextran Colloquial Name: Pig Iron	Iron deficiency anemia treatment	Nonemic, Ferrextran, Imposil, Uniferon		

I. Self-Regulatory Organization’s Statement of the Background, Purpose of, and Statutory Basis for the Proposed Rule Modification

The Horseracing Integrity and Safety Act of 2020 recognizes that the establishment of a national set of uniform standards for racetrack safety and medication control will enhance the safety and integrity of horseracing. The Act mandates and empowers the Authority to establish a uniform anti-doping and controlled medication program (“ADMC Program”) to improve the integrity and safety of horseracing in the United States. The Authority developed the proposed rules that constitute the ADMC Program and filed the proposed rules with the Commission on December 28, 2022. The proposed rules were published in the *Federal Register* on January 26, 2023,³ and were subsequently approved by the Commission by Order dated March 27, 2023.⁴

As part of the ADMC Program, the Authority developed the Rule Series 4000 Prohibited List. This includes a list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods. The Prohibited List uses as a baseline 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 (“IFHA”), including the IFHA International Screening Limits for urine and the IFHA International Screening Limits for plasma.

The Prohibited List identifies Prohibited Substances and Prohibited Methods that are: (a) prohibited at all times (“Banned Substances” and “Banned Methods”) on the basis of the Authority’s determination that medical, veterinary, or other scientific evidence or experience supports their actual or potential (i) ability to enhance the

³ See FTC, HISA Anti-Doping and Medication Control Rule, 88 FR 5070 (Jan. 26, 2023).

⁴ Order Approving the Anti-Doping and Medication Control Rule Proposed by the Horseracing Integrity and Safety Authority (Mar. 27, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/P222100CommissionOrderAntiDopingMedication.pdf.

performance in Covered Horses, (ii) masking properties, or (iii) detrimental impact on horse welfare; or (b) prohibited for Use on or Administration to a Covered Horse during the Race Period and prohibited to be present in a Post-Race Sample (which includes samples collected following a Covered Horserace or Vets' List Workout) or Post-Work Sample (which includes samples collected following a Timed and Reported Workout), except as otherwise specified in the Prohibited List (“Controlled Medication Substances” and “Controlled Medication Methods”). Prohibited Substances and Prohibited Methods may be included in the Prohibited List by general category (e.g., anabolic steroids) or by specific reference to a particular substance or method.

The “Technical Document – Prohibited Substances” (“Technical Document”), as an appendix to the Prohibited List (Rule Series 4000), supplements the Prohibited List and sets out additional detail concerning Prohibited Substances. The Technical Document enumerates specific Prohibited Substances that fall into the general categories listed in the Prohibited List and sets forth detection times, screening limits, and thresholds for those Prohibited Substances. The Technical Document also designates certain Prohibited Substances as Specified Substances, which are those that pose a higher risk of being the result of contamination and that are therefore subject to more flexible sanctions. The Authority proposes to modify the Technical Document to add iron dextran as a Banned Substance (S6).⁵ The proposed rule modification is described in detail in Section II of this publication.

In compliance with 16 CFR 1.142(a), the Authority states that the reason for adopting the proposed rule modification is to protect Covered Horses against the use of iron dextran. Use of iron dextran poses significant risks to the safety and welfare of Covered Horses, as outlined in the supporting documentation it attached as exhibits to its

⁵ Iron dextran is colloquially referred to as “pig iron.”

submission to the FTC.⁶ The designation of iron dextran as a Banned Substance will prohibit the use of iron dextran in Covered Horses.

The Authority is careful to consider all reasonable alternatives to a proposed rule modification. In this case, however, the obvious and only course available to protect Covered Horses from the hazards involved in the use of iron dextran is to ban its use.

The Equine Anti-Doping and Controlled Medication Protocol (“Protocol”) will affect Covered Persons, Covered Horses, and Covered Horseraces. The proposed rule modification will help to ensure that Covered Horseraces are conducted in a manner that is consistent with the highest standards of integrity and that prioritizes the safety of Covered Horses and Covered Persons. The welfare of Covered Horses will be secured by a rule that strictly prohibits the administration and possession of iron dextran, by categorizing it as a Banned Substance (S6). All Covered Persons will be subject to sanctions set forth in the Rule 3000 Series for failure to comply with the new ban.

To ensure this proposed rule modification is consistent with the Act and the rules and regulations applicable to the Authority, the Authority took the following principles and mandates into consideration. In accordance with 15 U.S.C. 3055(a)(2), which directs the Authority to consider the unique characteristics of any breed made subject to the Act by election of a State Racing Commission or breed governing organization, the Authority notes that proposed rule modification is applicable only to Thoroughbred horses, because other breeds are not currently subject to the jurisdiction of the Authority as Covered Horses. The supporting documentation submitted to the Commission along with this proposed rule modification sets forth the need for the prohibition of iron dextran because of its documented effect upon Thoroughbred horses in particular. In developing the

⁶ Those exhibits are available as a supporting document on the docket for this matter at <https://www.regulations.gov>.

proposed rule modification, the Authority accounted for the unique characteristics of Thoroughbred horses.

The Authority also considered the seven factors set forth in 15 U.S.C. 3055(b) and concluded that they support the addition of iron dextran to the list of Prohibited Substances.⁷

With reference to the baseline standards in 15 U.S.C. 3055(g)(2)(a), none of them address the regulation of iron dextran. The proposed rule modification would not render any rule in the Protocol less stringent than previously, because no rule in the Protocol currently addresses the regulation of iron dextran.

Due to the need to act quickly to preserve the safety of Covered Horses, the Authority did not solicit informal public comments in advance of submitting this proposed rule modification to the Commission. However, the Authority did consult with Dr. Dionne Benson, Chief Veterinary Officer for The Stronach Group, whose letter in support of the proposed rule modification⁸ can be found in the supporting documents section of the public docket for this publication on www.regulations.gov.

With the review, input, and ultimate approval of the Authority's Board of Directors, the proposed rule modification to the Rule 4000 Series Technical Document is

⁷ Those seven factors are: (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 Horseraces, 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 Horseraces should be uniform and uniformly administered nationally"; (4) "Consideration should be given to international anti-doping and medication control standards of the IFHA 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 upon 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 that 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." See the supporting documents on the docket at www.regulations.gov for the Authority's complete discussion of how these factors relate to the proposed rule modification concerning iron dextran.

⁸ Letter to HISA from Dionne Benson, DVM, JD, Chief Veterinary Officer for The Stronach Group, available among the supporting documents at www.regulations.gov.

submitted for Commission approval. As required by 15 U.S.C. 3053(b)(2), the proposed rule modification is consistent with the Act and the rules approved by the Commission. The Authority has consulted with the Horseracing Integrity and Welfare Unit (“HIWU”), the anti-doping and medication control enforcement agency with which the Authority has contracted to enforce the Protocol pursuant to 15 U.S.C. 3054(e)(1)(b). The HIWU has participated in the development of the proposed rule modification and approves of it.

II. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Modification

The Authority submits the proposed rule modification to the Technical Document to designate iron dextran and other iron dextran containing products as Banned Substances under the ADMC Program.

The risk of serious and potentially fatal adverse reactions to iron dextran products, together with its testing limitations, presents a risk of misuse and abuse in Covered Horses. Iron dextran products have Food and Drug Administration (“FDA”) approval only for the treatment and prevention of iron-deficiency anemia in swine. Iron and other blood-building supplements nonetheless are often administered to horses to maximize red blood cell count, with the belief that they will improve energy, stamina, and athletic performance. While the Animal Medicinal Drug Use Clarification Act of 1994, 21 U.S.C. 360b, is permissive of the extralabel use of FDA-approved products, the documented health risk of iron dextran to Covered Horses warrants its designation as a Banned Substance under the ADMC Program.

Iron dextran carries an increased risk of anaphylaxis and death in Thoroughbred racehorses, which has prompted some racetracks to ban possession of these substances. *See* Benson Letter at 1, *supra* (“Gulfstream Park and Palm Meadows recently prohibited the possession and/or use of injectable iron and injectable iron containing substances on track property. This occurred following the sudden death of several horses in the past two

years across all Stronach Group properties shortly after they had been administered injectable iron supplements.”); *see also* Thomas Tobin, MRCVS, Steven G. Kamerling, PhD, *Iron: Its Functions and Metabolism in the Horse*, 1986 (“Iron dextran injections should not be used to supplement iron. One author reported that two Thoroughbreds died within 15 hours of parenteral iron dextran injections, and in another case three horses died after the intramuscular injection of iron dextran. Similarly, the administration of supplements containing iron to neonatal foals has been suggested as a cause of death.”).⁹ Iron dextran may also pose a risk to a horse’s tissues and immune system. *See Tobin et al., supra*. Oral iron supplementation has not been associated with the same risk of anaphylaxis in horses as intramuscular injections.¹⁰

Further, to the extent anemia occurs in horses, it is likely associated with blood loss or an underlying health condition, as opposed to a primary iron deficiency. Thus, equine veterinary experts recommend identifying and treating the source of the anemia before administering an iron supplement and returning the horse to racing and training activities only after the anemia and its cause have resolved. *See Benson Letter, supra*.

Finally, monitoring and testing for iron dextran products in Covered Horses pose significant challenges, as iron is an endogenous mineral in the body. *See Benson Letter, supra*. Thus, it is critical that possession of iron dextran products be prohibited under the rules. By categorizing iron dextran as a Banned Substance under the ADMC Program, it will be prohibited under the Rule 3000 Series.

All the changes in the proposed rule modification are intended to enhance the Rule 4000 Series Technical Document in a manner consistent with the Act. The proposed

⁹ Supporting documents referenced in this publication can be found in the public docket for this publication on www.regulations.gov.

¹⁰ *See* Natalie Voss, *As Gulfstream Prohibits Injectable Iron, a Look at the Use of “Iron Shots,”* Paulick Report (Jan. 12, 2023), available at <https://paulickreport.com/horse-care-category/as-gulfstream-prohibits-injectable-iron-a-look-at-the-use-of-iron-shots/>.

rule modification is carefully tailored to the unique character of horseracing and to the regulation of Prohibited Substances in Covered Horses.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Commission must approve or disapprove the proposed modification on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. If approved, the proposed rule modification would be effective immediately.

IV. Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before [INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Write “HISA Anti-Doping and Medication Control Rule Modification” on your comment. Your comment – including your name and your state – will be placed on the public record of this proceeding, including the <https://www.regulations.gov> website.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we strongly encourage you to submit your comments online. To make sure the Commission considers your online comment, you must file it at <https://www.regulations.gov>, by following the instructions on the web-based form.

If you file your comment on paper, write “HISA Anti-Doping and Medication Control Rule Modification” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex H), Washington, DC 20580. If possible, please submit your paper comment to the Commission by overnight service.

Because your comment will be placed on the publicly accessible website at <https://www.regulations.gov>, you are solely responsible for making sure your comment

does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's 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. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "any trade secret or any commercial or financial information . . . which is privileged or confidential." 15 U.S.C. 46(f); *see* FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, your comment should not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at <https://www.regulations.gov>, as legally required by FTC Rule 4.9(b), 16 CFR 4.9(b), we cannot redact or remove your comment, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), 16 CFR 4.9(c), and the General Counsel grants that request.

Visit the FTC website to read this publication and the news release describing it. The FTC Act and other laws the Commission administers permit the collection of public

comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments it receives on or before [INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL* REGISTER]. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

April J. Tabor,

Secretary.

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