PUBLIC

**UNITED STATES OF AMERICA**
**BEFORE THE FEDERAL TRADE COMMISSION**
**OFFICE OF ADMINISTRATIVE LAW JUDGES**
**FTC DOCKET NO. 9435**

**ADMINSTRATIVE LAW JUDGE: JAY L. HIMES**

**IN THE MATTER OF:**

**DR. SCOTT SHELL, DVM** **APPELLANT**

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# APPELLANT'S SUPPORTING LEGAL BRIEF

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**Andrew J. Mollica, Esq.**
1205 Franklin Ave Suite 16LL
Garden City, New York 11530
516 528-1311 Cell
516 280-3182 Office
jdmol@aol.com
**ATTORNEY FOR APPELLANT**

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Appellant, Dr. Shell, submits this legal brief in support of his Proposed Findings of Fact, Proposed Conclusions of Law, and Proposed Order.

## I. Introduction

The Horseracing Integrity and Safety Authority ("**HISA**") and Horseracing Integrity & Welfare Unit ("**HIWU**"), failed to meet their burden to demonstrate a bottle labeled "Hemo 15" confiscated from Appellant ("**Bottle**") and/or 228 self-reported "Hemo 15" administrations to 37 Covered Horses, is and/or contained a Banned Substance, and/or was a violation of Anti-Doping and Medication Control ("**ADMC**") Program Rule ("**Rule**")[1] 4111, S0 Non-Approved Substances, and Rule 3214(c), Administration of Banned Substances to a Covered Horse. The only evidence of Appellant's "Hemo 15" contents was a lab report, revealing no Banned Substances.[2]

The Arbitrator erred in finding[3] Appellant's "Hemo 15," a vitamin supplement, violated Rule 4111 as it makes no label claims to treat any condition, is not a drug, and without a claim, it cannot have and does not need government/FDA approval, and this complies with and/or renders Rule 4111 inapplicable, including the Animal Medicinal Drug Use Clarification Act ("**AMDUCA**"), which addresses extra-label use of FDA approved drugs, and FDA Guidance for Industry ("**GFI**") #256 (also known as Compounding Animal Drugs from Bulk Drug Substances).

Notwithstanding expert opinions, Rule 4111, the Decision, and the Civil Sanction are arbitrary and capricious as unreasonable, unsupported by substantial evidence, and violative of Appellant's due process rights under the United States Constitution as there is no notice of what substances are banned and/or how a substance, like Appellant's Hemo-15, making no drug claims, becomes a drug, and is a Banned Substance. Appellant is faultless.

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[1] Hereinafter, "**Rule(s)**."
[2] **Proposed Finding of Fact** (hereinafter, "**PFF") 4-8.**
[3] Arbitrator Hon. Hugh Fraser's ("**Arbitrator**") June 11, 2024, Amended Decision, JAMS Case No. 1501000708 ("**Decision**"). **PFF 36.**

Finally, the Fifth Circuit decision in *National Horsemen's Benevolent and Protective Association v. State of Texas,* 107 F.4th 415 (5th Cir. 2024) ("***NHPB***"), finding HISA enforcement unconstitutional, is a better reasoned than the Sixth Circuit decision, *Oklahoma v. United States*, 62 F.4th 221 (6th Cir. 2023), cert. denied, 2024 U.S. LEXIS 2724 (June 24, 2024) ("***Oklahoma***"), which found constitutionality in a facial challenge. HISA/HIWU enforcement violates private nondelegation doctrine, facially, and as applied to Appellant, as private entities oversaw enforcement, did not function subordinately to the FTC, and Appellant's injury cannot be rectified by post-arbitration rule making.

## II. De Novo Review

Appellant seeks review under 15 U.S.C. § 3058(b)(2)(A), requiring the law judge to determine *de novo* whether: (i) Appellant engaged in such acts or practices…as the Authority has found…(ii) [whether] such acts, practices, or omissions are in violation of the [ADMC Program Rules]; or (iii) [if] the final civil sanction of the Authority was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 15 U.S.C. § 3058(b)(2)(A)(i)-(iii).

## III. The Agency Did Not Meet Their Burden to Show Administration of a Banned Substance

The Arbitrator erroneously concluded HISA and HIWU met their burden to establish Appellant administered Banned Substances to Covered Horses, by more than a preponderance of the evidence. Rule 3121. **15 U.S.C. § 3058(b)(2)(A)(1)(i).**

### A. There Was No Evidence of a Banned Substance

HIWU charged Appellant based on HISA Portal records showing 228 self-reported administrations of "Hemo 15." **PFF 17-18, 20.** Hemo 15 is shorthand for a group of vitamins, amino acids, and minerals. **PFF 14.** Hemo 15 is not on HISA's Banned Substance list. **PFF 13.**

The only evidence of the contents of Appellant's "Hemo 15," was a PETRL Report,

analyzing a Bottle labeled "Hemo 15," confiscated from Appellant on October 4, 2023. **PFF 2-4.** The PETRL Report did not identify Banned Substances. **PFF 5-11.** Appellant's Hemo 15 is not trademarked Hemo 15® available in Europe. **PFF 30.** The Bottle identified pharmacy Horse Necessities, Inc., where Appellant obtained all his Hemo 15, and ingredients were the same for 37 years. **PFF 3, 16.**

One substance found of concern was Cobalt. **PFF 5**. Dr. Scollay agreed Cobalt is a trace mineral found in Vitamin B-12, potential derivative of other constituents, **PFF 6**, that there was no evidence of "Cobalt Salt," a Banned Substance, **PFF 8**, and that HISA has a threshold for Cobalt in a horse's blood (or urine) and there was no evidence it was met. **PFF 7.** Dr. Scollay expressed "significant interest" in nicotinamide, which is not on the Banned Substance list, and is "under investigation" as to whether it is a metabolite of Vitamin B-12 or a contaminant of formulating vitamin products. **PFF 9-11.** Dr. Scollay used the word "banned," but admitted, "as of yet," nicotinamide is on a "monitoring list." **PFF 9**. Absent further analysis of nicotinamide, the PETRL Report is not evidence of a Banned Substance violation, only of "significant interest." **PFF 11.**

While HISA/HIWU can charge based on records, they did not meet their burden to show a Rule 3214(c) or 4111 violation as there is no evidence Appellant's Hemo 15 or its constituents contained/were Banned Substances that were administered and reliance on a shorthand name is no evidence at all.

**B. The Decision was Unreasonable and Not Based on Substantial Evidence**

The Decision and Civil Sanction based on the name "Hemo 15," not its contents, is arbitrary and capricious because it is "[im]possible to offer a reasoned explanation," *see Killian v. Healthsource Provident Adm'rs*, 152 F.3d 514, 520 (6th Cir. 1998), why Appellant's Hemo 15 is banned, without evidence that what is in that Hemo 15 is banned. **PFF 6-12.** The Decision is not

based on "substantial evidence" *Killian,* 152 F. 3d at 520. Substantial means "less than a preponderance but more than a scintilla; it refers to relevant evidence that a reasonable mind might accept as adequate to support a conclusion." *See, Gentry v. Commr. of Social Sec*., 741 F3d 708, 722 (6th Cir. 2014). Finding Appellant's "Hemo 15" to be a banned based on name alone is arbitrary and capricious as it is unreasoned, cannot support the conclusion, and is not evidence, **PFF 5-12,** let alone "substantial" or a preponderance of the evidence. Thus, the Decision should be reversed and Civil Sanction vacated, as the Agency did not meet its burden to show the "Hemo 15" confiscated and/or administered by Appellant contained or was a Banned Substance.

**C. Dr. Shell's Hemo-15 is Complaint with and/or Rule 4111 is Inapplicable**

The Arbitrator erroneously found HISA met its burden to show Appellant's administration of Hemo-15 was "a violation" of Rule 4111. **15 U.S.C. § 3058(b)(2)(A)(1)(ii).** Hemo 15 is not on the Banned Substance list, **PFF 13.** HIWU charged Appellant under catchall, Rule 4111. "S0 Non-Approved Substances," which are:

> Any pharmacological substance that (i) is not addressed by Rules 4112 through 4117, (ii) has no current approval by any governmental regulatory health authority for veterinary or human use, and (iii) is not universally recognized by veterinary regulatory authorities as a valid veterinary use, is prohibited at all times. For the avoidance of doubt, compounded products compliant with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Guidance for Industry (GFI) #256 (also known as Compounding Animal Drugs from Bulk Drug Substances) are not prohibited under this section S0.

**PFF 20.**

The Arbitrator unreasonably failed to appreciate the most significant fact - "Hemo 15" confiscated and/or used by Appellant, compounded in the United States, makes no label claims of treatment for any condition. **PFF 15, 26**. Appellant administered "Hemo 15" as a vitamin supplement not for specific conditions. **PFF 24-25**. Therefore, Appellant's Hemo 15 is not a drug

and is compliant with and/or Rule 4111 is inapplicable. In this context, compliant means not offending the rule.

***First***, Appellant's "Hemo 15" is not addressed by Rules 4112 through 4117. **PFF 33.** ***Second***, Dr. Scollay admitted that to be considered a drug, there must be a claim to treat a condition, the FDA does not give or require vitamin approval, and HISA can't require them to be approved, including vitamins, dietary supplement, minerals, electrolytes, amino acids, unless they make claims thereby meeting the definition of a drug. **PFF 21.** Appellant's Hemo 15, which makes no claims, contained vitamins, minerals and amino acids, and no per-se-Banned constituents, is not a drug, cannot have government/FDA approval and HISA cannot require it. **PFF 21, 31.** Trademarked European Hemo 15® has nothing to with FDA claims in the United States. **PFF 31**. Therefore, Rule 4111(ii) requiring government approval is either satisfied or inapplicable because Appellant's "Hemo 15" cannot have FDA approval, and HISA cannot require it. **PFF 21, 31.**

If a judge is "confident that the decisionmaker overlooked something important or seriously erred in appreciating the significance of the evidence…it may conclude that a decision was arbitrary and capricious." *Erickson v. Metropolitan Life Ins. Co.,* 39 F.Supp.2d 864, 870 (E.D. Mich. 1999). The Arbitrator's serious failure to recognize the importance of the absence of drug claims on Appellant's Hemo 15's label, or anywhere else, renders the Decision erroneous, arbitrary and capricious.

***Third,*** while Hemo 15 does not need regulatory approval, Drs. Bertone and Shell testified Hemo 15 has wide use as a vitamin supplement, and it acceptable in the veterinary community, i.e., United States. **PFF 26, 31.**

***Fourth***, the failure to properly appreciate that Appellant's Hemo 15 makes no claims, and is not a drug, tainted the Decision because the Arbitrator unreasonably credited HIWU's expert

analysis under Rule 4111, ADMUCA and GFI # 256. **PFF 27-28, 36.**

HIWU's experts incorrectly presupposed that Hemo-15 is a drug in making their conclusions. Dr. Maxwell and the Arbitrator cited to, "[f]oreign Hemo-15® products," which makes claims. **PFF 30.** Dr. Maxwell opined Hemo 15 is a new animal drug because it is "intended to cure, mitigate, treat, or prevent a disease…" **PFF 27.** But as Dr. Bertone stated, you cannot impute intent as the claim to treat must be on the label. **PFF 31.** Absent a drug claim, Dr. Maxwell's conclusion that it is a "new animal drug" based on "inten[t] to cure" is wrong as a matter of law. Dr. Maxwell admits AMDUCA relates to extra-label use of FDA approved drugs, thus this is wholly inapplicable. **PFF 28.** Dr. Maxwell admits GFI #256 deals with compounding drugs from drug or "bulk drug substances." **PFF 28.** Appellant did not compound from drugs or "bulk drug substances," as that term is defined because you cannot impute intent to cure (i.e., cobalt deficiency) or treat to Appellant's Hemo 15 or its constituents. **PFF 29, 31, 36.**

Dr. Sharlin's presupposed that Appellant's Hemo 15 is a drug. In his discussion of a chart for GFI #256, he states the "first question to consider…is whether the compounded drug in issue was created to fulfill a prescription for a specific animal." **PFF 36.** Dr. Sharlin stated "[t]here are two possible sources for the active ingredient in a compounded drug: an **FDA-approved drug, or a bulk drug substance**." **PFF 36** (bold added). Dr. Sharlin agreed with Dr. Bertone that it is the claim that makes a substance a drug in terms of FDA approval, **PFF 35,** but then opined about an "end-run" around FDA regulations because compounded "drug" labels don't require listing a claim, without HISA/HIWU showing Appellant's Hemo 15 is compounded from "drugs" or made of a "bulk drug substance(s)," which claims to diagnose or cure. **PFF 36.** While the FDA expressed concerns about injectable vitamins, injection of a vitamin supplement does not turn it into a drug without a label claim. **PFF 35-36.** While Dr. Scollay pointed to Appellant's Hemo 15 label, which

states "…this is a compounded drug. Not an FDA approved or indexed drug", Dr. Bertone testified this is a standard statement and wrong as to Appellant's Hemo 15. **PFF 12.**

It is incorrect to analyze Appellant's Hemo 15 under AMDUCA and/or GFI # 256 because it is not a new animal drug, because drugs must make claims. **PFF 35.** AMDUCA does not apply because it is an off-label drug use act. **PFF 28 and 35.** Further, Appellant's Hemo 15 is compliant with GFI # 256 because Appellant is not compounding from drugs or "bulk drug products," (which definitionally must claim to treat) the FDA website allows for compounding from "pharmacy products," and there are records of individual use, and/or GFI # 256 does not apply. **PFF 35-36**.

Each conclusion reached by HIWU's experts under AMDUCA and/or GFI # 256 is invalid because it presupposes Hemo 15 requires government approval, or that it or its parts are drugs without demonstrating they are. The Arbitrator erred, acted arbitrary and capriciously, in failing to accord the lack of drug claims proper weight, credited HIWU experts in error, and under 15 U.S.C. § 3058(b)(2)(A)(1)(ii), HISA/HIWU failed to meet their burden to show a violation of Rules 4111 or 3214(c).

## IV. Rule 4111, the Charges and the Decision Violate Dr. Shell's Due Process Rights and/are Arbitrary and Capricious

The Arbitrator did not address Appellant's argument that Rule 4111 violates Appellant's Fifth and Fourteenth Amendment constitutional due process rights. *Belle Maer Harbor v Charter Twp. of Harrison*, 170 F3d 553, 556 (6th Cir. 1999). ("Fifth and Fourteenth Amendments provide the constitutional foundation for the void-for-vagueness doctrine"). Due process requires notice of forbidden conduct. *FCC v. Fox TV Stas., Inc.,* 567 U.S. 239, 253 (2012). A rule forbidding "an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law." *Connally v. Gen. Constr. Co.,* 269 U.S. 385, 391 (1926). This applies to administrative law. *County of Suffolk v. First*

*American Real Estate*, 261 F.3d 179, 195 (2d Cir. 2001); *Peoples Rights Org. v City of Columbus*, 152 F.3d 522 (6th Cir 1998) A rule may be challenged as void-for-vagueness either on its face or as applied. *United States v. National Dairy Products Corp*., 372 U.S. 29, 36 (1963). Due process is violated if a vague regulation even encourages arbitrary enforcement. *City of Chicago v. Morales*, 527. U.S. 41, 56 (1999). Notice is not presumed where the statute is "so technical or obscure that it threatens to ensnare individuals engaged in apparently innocent conduct." *United States v. Blaszak,* 349 F.3d 881, 886 (6th Cir. 2003).

**A. Due Process**

Notwithstanding expert opinion, Covered Persons of reasonable intelligence cannot understand what substances, including Appellant's Hemo 15, are subject to Rule 4111. The rule is facially unclear, and as applied to Appellant, because it unclear, how, or whether a substance or any substance that is not subject to FDA approval because it makes no drug claims, is subject to the rule, compliant with, or satisfies government approval requirements when approval is not required or cannot be had, or if and how Rule 4111 turns substances with no claims into a drugs requiring approval. **PFF 26.** Rule 4111 lacks definitions, including for "universally recognized," "valid veterinary use" and "compliant". *See* Rule 4111.

The mere fact that FDA experts and veterinarians disagree as to how to apply Rule 4111 shows a Covered Person of reasonable intelligence cannot understand its meaning. **PFF 26-36.** The rule requires uber-technical analysis, *see Blaszak,* 349 F.3d at 886, invokes confusion as to whether AMDUCA or GFI #256 apply, if and how Rule 4111 turns vitamins, minerals and amino acids into drugs, absent a claim, the effect of injection, the effect of compounding individually and for office use, and how compounding from non-drug substances even implicates AMDUCA or GFI #256. **PFF 26-35.**

Moreover, GFI #256 is "guidance" -- not law, **PFF 32**, requiring assumptions, and the words "compliant with…GFI #256" are meaningless as you can veer from guidance but still be "compliant" with GFI # 256. HISA will argue that Court of Arbitration for Sport cases like *IAAF v. RFEA & Josephine Onyia,* CAS 2009/A/1805 and *Jakub Wawrzyniak v. HFF*, CAS 2009/A/2019 ¶ 24. demonstrate that Appellant can understand Rule 4111. But in *IAAF*, the rule was clear stimulants and "all related substances with a similar chemical structure or similar biological effect" were banned. ¶ 90. The same type of clear rule was reviewed in *Wawrzyniak.*

Dr. Bertone testified that unlike Dr. Sharlin and himself (FDA experts), the public and veterinarians have relatively no understanding of the issues contained in Rule 4111. **PFF 35**. As FDA and veterinary experts must give opine how to apply Rule 4111– it is vague on its face, as applied to Appellant, and violates due process.

**B. Arbitrary and Capricious**

The Arbitrator erroneously concluded that because "no other veterinarian has been charged with the administration of Hemo 15," the rule can be "understood by Covered Persons of ordinary intelligence and is [not] arbitrary and capricious." **PFF 37**. Due process and arbitrary and capricious are related. Arbitrary enforcement is encouraged "by failing to describe with sufficient particularity what a [person] must do in order to satisfy the statute" *Kolender v. Lawson*, 461 U.S. 352, 361 (1983). In the absence of clear rules, agency decisions are arbitrary and capricious. *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009) ("An agency may not . . . depart from a prior policy sub silentio..."); *Beckles v. United States*, 580 U.S. 256, 266 (2017) (vague law invites arbitrary enforcement as it "leaves judges [] free to decide, without any legally fixed standards, what is prohibited and what is not").

Experts disagree as to how, if, and when Rule 4111 applies, and disagree what happens

when a substances do not make a drug claims or need FDA approval. **PFF 26-35**. Rule 4111 is not a clear rule, *Fox*, 556 U.S. at 515 and it grants unfettered discretion to depart from HISA/HIWU policy statements that vitamin and supplements without drug claims do not need FDA approval. *See Fox*, 556 U.S. at 515; **PFF 21**. Rule 4111 lacks fixed standards, relies on GFI # 256 guidance, requiring expert assumptions, and leaves judges to decide *ad hoc* what is prohibited. *See Beckles*, 580 U.S. at 266, which encourages arbitrary enforcement and violates due process.

The Arbitrator's Decision and Civil Sanctions are also arbitrary and capricious because they are unreasoned and are not based on substantial evidence. *Killian*, 152 F. 3d at 520. The Arbitrator speculated as to why no other veterinarian reported Hemo 15. **PFF 36-37**. There is no basis to conclude Rule 4111 was understandable because only Appellant self-reported Hemo 15. It is equally possible other veterinarians reported it as a vitamin. **PFF 37**. Thus, Rule 4111, the Decision and Civil Sanction are arbitrary, capricious, prejudicial and contrary to law.

### C. The Civil Sanction is Arbitrary and Capricious, and Contrary to Law Based on Unreasoned Apportionment of Fault

The Decision and Civil Sanction are also arbitrary and capricious because the Arbitrator found Appellant at fault for not recognizing or asking if Hemo 15 was a Banned Substance, but held it was understandable that he continued administration of the substance after his initial reporting without warning or consequence (for approximately five months) and he was not charged for almost seven months. **PFF 39.**

This conclusion is illogical. Appellant did due diligence and for the same reason he bears no fault for the subsequent 227 administrations -- he is faultless for the first administration – ***because he had no notice Hemo 15 was banned.*** **PFF 19, 23.** It is HISA/Congress' obligation to promulgate clear rules – not Appellant's to ask. *Fox, supra.* There was no notice under the Banned Substance List, **PFF 15**, and Rule 4111 is incomprehensible. If HISA/HIWU is blameworthy for

the 227 subsequent administrations, and Appellant blameless because he had no assurance for those 227 counts, the same is true for Count One. The Decision and the resulting Civil Sanctions are all inextricably linked, Dr. Shell is faultless, and these arguments should be considered, with a finding that Rule 4111, the charges (including 3214(c)), the Decision and Civil Sanctions are arbitrary and capricious, contrary to law, and should be reversed and vacated.

## V. HISA and HIWU's Enforcement Violates the Private Nondelegation Doctrine

The Fifth Circuit case *NHPB,* 107 F.4th 415 (5th Cir. 2024) finding that private entities enforcing HISA unconstitutionally violates the private nondelegation doctrine because they do not function subordinate to the FTC -- is a better reasoned, compared to *Oklahoma*, 62 F.4th 221, which found HISA to be constitutional.

"A private entity may wield government power only if it 'functions subordinately' to an agency with 'authority and surveillance' over it." *NHBPA*, 107 F.4th at 423. While *Oklahoma* is law in the Sixth Circuit, a reasoned review of both cases demonstrates why *Oklahoma* should be overturned and charges against Appellant dismissed for violation of the private nondelegation doctrine - *as applied to Appellant.*

First, the Sixth Circuit did not have the benefit of the *NHPBA* decision, decided after *Oklahoma*. The Fifth Circuit agreed with Sixth Circuit in all material respects accept one, that "HISA is enforced by a private entity, the Authority [which] decides whether to investigate a covered entity for violating HISA's rules…[and] decides whether to sanction it…" *NHPBA,* 107 F.4th at 429.

HISA does not empower the FTC to decide whether to investigate or charge. *NHPBA*, 107 F.4th at 429. "It is no answer to say that the FTC can come in at the tail-end of this adversarial process and review the sanction." *NHPBA*, 107 F.4th at 430. It is clear from *NHPBA* that *Oklahoma*

concerned a facial challenge to HISA, and it was "persuaded…that at least a facial challenge to the Authority's enforcement powers should fail," *NHPBA*, 107 F.4th at 431, because through § 3053(e) rulemaking, "the FTC could subordinate every aspect of the Authority's enforcement," *Id*. The Fifth Circuit acknowledge rule making has some "purchase power in turning back the clock," but concluded that rule making cannot "save the Authority's enforcement powers." *Id.*, as "HISA's clear delineation of enforcement power" cannot be altered through rulemaking and on its face "oversight [happens] only after the enforcement process is over and done with…" *NHPBA*, 107 F.4th at 433. Thus, the Fifth Circuit analysis is better reasoned in terms of how enforcement is actually conducted.

While Appellant argues *NHPBA* is better reasoned in terms of a facial challenge, the Sixth Circuit did not address as-applied challenges. As applied to Appellant, the rule clearly violates the non-delegation doctrine. Appellant was subject to HISA/HIWUs arbitrary enforcement of Rule 4111, which violates due process. The Appellant now stands before Judge Himes, after imposition of the Civil Sanction, and after other reputational damage. Rulemaking will do little to rectify this damage and the unconstitutional charges should be dismissed.

## VI. Conclusion

The Decision should be reversed, the Civil Sanctions vacated, and the charges dismissed with prejudice.

Dated: September 11, 2024

Respectfully Submitted,
***/s/ Andrew Mollica***
Andrew J. Mollica, Esq.
1205 Franklin Ave Suite 16LL
Garden City, New York 11530
516 528-1311 Cell
516 280-3182 Office
jdmol@aol.com

**WORD COUNT AND SPECIFICATIONS CERTIFICATION**

I Andrew Mollica, Esq. certify that the above Brief in Support of Proposed Findings of Fact, Proposed Conclusion of Law and Proposed Order were prepared using a computer, Microsoft Word Program, that I used Times New Roman Font, double spaced text, and that I conducted a word count with the Microsoft program, and not including caption, cover page, signatures, service documents, this document is **3,744 words**, including footnotes.

**September 11, 2024**

/s/ ***Andrew Mollica***
Andrew J. Mollica

## CERTIFICATE OF SERVICE

Pursuant to 16 CFR §1.146(a) and 16 CFR §4.4(b), a copy of this Appellant's Brief in Support of Proposed Findings of Fact, Conclusion of Law and Proposed Order, is being served on this September 11, 2024, via Administrative E-File System and by emailing a copy to:

| | |
|---|---|
| Allison J. Farrell<br>Michelle C. Pujals<br>Horseracing Integrity & Welfare Unit<br>4801 Main Street, Suite 350<br>Kansas City, MO 64112-2749<br>afarrell@hiwu.org<br>mpujals@hiwu.org<br>**COUNSEL FOR HIWU**<br>**A Division of Drug Free Sport, LLC** | James Bunting<br>Alexandria Matic<br>Tyr LLP<br>488 Wellington Street West,<br>Suite 300-302<br>Toronto, ON M5V1E3 Canada<br>jbunting@tyrllp.com<br>amatic@tyrllp.com<br>**COUNSEL FOR HIWU** |
| Hon. Jay L. Himes<br>**ADMINISTRATIVE LAW JUDGE**<br>Office of Administrative Law Judges<br>Federal Trade Commission<br>600 Pennsylvania Avenue NW<br>Washington, DC 20580<br>Via email to oalj@ftc.gov | April Tabor<br>Office of the Secretary<br>Federal Trade Commission<br>600 Pennsylvania Avenue, NW<br>Suite CC-5610<br>Washington, DC 20580<br>Via email: electronicfilings@ftc.gov |
| BRYAN BEAUMAN<br>REBECCA PRICE<br>333 W. Vine Street, Suite 1500<br>Lexington, Kentucky 40507<br>bbeauman@sturgillturner.com<br>rprice@sturgillturner.com<br>**HISA ENFORCEMENT COUNSEL** | |

***/s/ Andrew J. Mollica***
Andrew J. Mollica, Esq.