

Ltd; Azamara Cruises; Carnival Cruise Lines; Celebrity Cruises, Inc.; Costa Cruise Lines; Crystal Cruises; Cunard Line; Disney Cruise Line; Emerald Cruises; Explora SA; Hapag-Lloyd Kreuzfahrten GmbH; Heritage Expeditions; Holland America Line; Marella Cruise; MSC Cruises; NCL Corporation; Oceania Cruises; P&O Cruises; Pearl Seas Cruises; Ponant Yacht Cruises & Expeditions; Princess Cruises; Regent Seves Seas Cruises; Royal Caribbean International; Sea Cloud Cruises GmbH; Seabourn Cruise Line; Seadream Yacht Club, Ltd.; Star Cruises (HK) Limited; Swan Hellenic; Virgin Voyages; and Windstar Cruises.

*Filing Party:* Marissa Rivera, Cruise Lines International Association.

*Synopsis:* The amendment updates the membership of the agreement and revises the agreement to divide Global Members between Global Holding Members and Global Operating Members and specifies the difference between them.

*Proposed Effective Date:* 6/11/2023.

*Location:* <https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/999>.

Dated: April 28, 2023.

**JoAnne O'Bryant,**

*Program Analyst.*

[FR Doc. 2023-09387 Filed 5-2-23; 8:45 am]

**BILLING CODE 6730-02-P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than May 18, 2023.

A Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) One Memorial Drive, Kansas City, Missouri 64198. Comments can also be electronically to [KCApplicationComments@kc.frb.org](mailto:KCApplicationComments@kc.frb.org):

1. *Steven R. Niemack, individually, and as trustee of the Steven R. Niemack Revocable Living Trust dated 3-25-2021 and the Steven R. Niemack Family Irrevocable Trust dated 1-31-2011, all of Lawrence, Kansas;* to form the Niemack Family Group, a group acting in concert, to retain voting shares of Maple Hill Bancshares, Inc., and thereby indirectly retain voting shares of Stockgrowers State Bank, both of Maple Hill, Kansas.

Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Deputy Associate Secretary of the Board.*

[FR Doc. 2023-09368 Filed 5-2-23; 8:45 am]

**BILLING CODE P**

## FEDERAL TRADE COMMISSION

### Horseracing Integrity and Safety Act: Anti-Doping and Medication Control Rule

**AGENCY:** Federal Trade Commission.

**ACTION:** Notice of Horseracing Integrity and Safety Authority (HISA) final rule; delay of effectiveness.

**SUMMARY:** The Federal Trade Commission modifies the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Rule by extending its date of effectiveness until May 22, 2023.

**DATES:** As of May 3, 2023, the date of effectiveness for the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Rule is delayed to May 22, 2023.

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

**SUPPLEMENTARY INFORMATION:**

#### I. Reason for Delay of HISA's Final Rule

The Horseracing Integrity and Safety Act of 2020, 15 U.S.C. 3051-3060 ("Act"), tasks a self-regulatory nonprofit

organization, the Horseracing Integrity and Safety Authority ("Authority"), with developing proposed rules on a variety of subjects. *See* 15 U.S.C. 3053(a). Those proposed rules take effect only if approved by the Federal Trade Commission, *see* 15 U.S.C. 3053(b)(2), which must approve the proposed rules if it finds that they are consistent with the Act and with applicable rules approved by the Commission, *see* 15 U.S.C. 3053(c)(2). The Commission, however, may by rule abrogate, add to, or modify the Authority's rules "as the Commission finds necessary or appropriate to ensure the fair administration of the Authority, to conform the rules of the Authority" to the Act's requirements or applicable rules approved by the Commission, "or otherwise in furtherance of the purposes of this Act." *Id.* sec. 3053(e).

On March 27, 2023, the Commission issued an Order ("Order") approving the Authority's proposed Anti-Doping and Medication Control ("ADMC") Rule. Pursuant to that Order, the ADMC Rule took effect immediately upon the Commission's approval, *i.e.*, on March 27, 2023.<sup>1</sup>

On March 31, 2023, however, the United States District Court for the Northern District of Texas determined that the Commission had violated the Administrative Procedure Act by declaring the ADMC Rule effective immediately upon the issuance of the Commission's Order approving the Rule. Viewing the Commission's March 27 Order as tantamount to an agency's issuance of a substantive rule, the court found that the Commission should have delayed the date of effectiveness for the ADMC Rule for 30 days following approval. The court accordingly enjoined implementation or enforcement of the ADMC Rule until May 1, 2023.<sup>2</sup>

The district court's March 31 order has given rise to substantial uncertainty regarding the criteria and procedures under which anti-doping and medication control protocols will be implemented as the Thoroughbred horseracing industry nears the Triple Crown events of May 6 (Kentucky Derby), May 20 (Preakness Stakes), and June 10 (Belmont Stakes). With the date of effectiveness for the Authority's nationally applicable ADMC Rule

<sup>1</sup> *See* Fed. Trade Comm'n, Order Approving the Anti-Doping and Medication Control Rule Proposed by the Horseracing Integrity & Safety Auth. (Mar. 27, 2023), [https://www.ftc.gov/system/files/ftc\\_gov/pdf/P222100CommissionOrderAntiDopingMedication.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/P222100CommissionOrderAntiDopingMedication.pdf).

<sup>2</sup> *Nat'l Horsemen's Benevolent & Protective Ass'n et al. v. Jerry Black et al.*, No. 5:21-CV-071-H, 2023 WL 2753978 (N.D. Tex. Mar. 31, 2023).

suspended by the district court until May 1, the conduct of anti-doping and medication control will remain under the jurisdiction of the various state racing authorities until that date, with the Authority's jurisdiction resuming only five days before the Kentucky Derby and nineteen days before the Preakness. Because the ADMC Rule governs the treatment of horses weeks before a covered race, some affected parties who are treating horses in a manner consistent with state requirements may find it difficult to come into compliance in the five days between the ADMC Rule's scheduled date of effectiveness and the Kentucky Derby on May 6.<sup>3</sup> Even in the absence of conflicts between the ADMC Rule and applicable state regulations, implementing new testing requirements just days before the start of the Triple Crown creates an appreciable risk of errors, confusion, and inconsistent treatment of similarly situated horses—harms that could frustrate the purposes of the Act.

In light of these policy concerns, the Commission finds it necessary to modify HISA's ADMC Rule, pursuant to the recently revised 15 U.S.C. 3053(e), to ensure the "fair administration of the Authority" and otherwise in furtherance of the Act's purposes. Accordingly, pursuant to the authority granted to the Commission by 15 U.S.C. 3053(e), the Commission issues this document delaying the date of effectiveness for the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Rule until May 22, 2023.

## II. Administrative Procedure Act

As noted above, the Act authorizes the Commission to abrogate, add to, or modify the Authority's rules for specified reasons, including "to ensure the fair administration of the Authority." 15 U.S.C. 3053(e). This provision authorizes Commission rulemaking pursuant to section 553 of Title 5, the Administrative Procedure Act (APA). The APA typically provides for notice-and-comment rulemaking, but under section 553(b)(3)(B) of the APA, general notice and the opportunity for public comment are not required with respect to a rulemaking when an "agency for good cause finds (and

incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."<sup>4</sup>

Here, the Commission finds, for good cause, that notice and comment is impracticable and unnecessary with respect to the document. Given the short time remaining before commencement of the Triple Crown races, providing advance notice would delay the effect of HISA's final rule until after the Kentucky Derby, defeating the rule's purpose. Obtaining comments after issuance of the rule is unnecessary because the full effect of the Commission's rule—which merely provides for a brief delay in the date of effectiveness for the ADMC Rule—will have occurred prior to the Commission's collection and consideration of any comments.

For these reasons, the Commission finds that there is good cause consistent with the public interest to issue the document without notice and comment.<sup>5</sup> The Commission therefore issues the document without prior notice and comment.

The APA also requires a 30-day delayed effective date, except for "(1) substantive rules which grant or recognize an exemption or relieve a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause."<sup>6</sup> For the same reasons noted with regard to notice and comment, and because extending the date of effectiveness for the ADMC Rule relieves a restriction, the Commission finds there is good cause for its document to take effect immediately.

## III. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act (PRA), an agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget control number. This document issued by the Commission—which addresses solely the date of effectiveness for the Authority's ADMC Rule—does not involve any collection of information pursuant to the PRA.

## IV. Regulatory Flexibility Act and Congressional Review Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires that the

Commission provide an Initial Regulatory Flexibility Analysis (IRFA) with a proposed rule and a Final Regulatory Flexibility Analysis (FRFA), if any, with a final rule. However, this obligation does not apply when an agency for good cause determines that a rulemaking is not subject to notice and comment. *See, e.g., Or. Trollers Ass'n v. Gutierrez*, 452 F.3d 1104, 1123–24 (9th Cir. 2006). The Commission finds that good cause exists for adopting this document without advance public notice or an opportunity for public comment. Because notice and comment are not statutorily required, the requirement to publish an analysis under the RFA does not apply to this document.

Pursuant to the Congressional Review Act (5 U.S.C. 801 through 808), the Office of Information and Regulatory Affairs has said that it would presumptively treat the type of rulemaking that the Commission announces today as not a "major rule" (as defined in 5 U.S.C. 804(2)). The Commission occasionally extends a compliance date for a new rule or rule amendment to give entities additional time to prepare for compliance. For example, in 2010, the FTC extended the compliance date for its Energy Labeling Rule (16 CFR part 305) (formerly, Appliance Labeling Rule) to give regulated entities additional time to incorporate new labeling requirements for light bulbs into product packaging. *See* 75 FR 81943 (Dec. 29, 2010); 76 FR 20233 (Apr. 12, 2011). The Office of Management and Budget has previously designated such extensions as "not major." Because such amendments merely defer the expected economic effects of a previously adopted rule, any costs and benefits associated with the compliance date extension should be incremental to those already considered in connection with the promulgation of the underlying rule. For similar reasons, the relief should not result in major cost increases or significant adverse effects on competition, investment, or innovation. In addition, for purposes of this category, presumptively "not major" rules would be those in which the compliance date extension is limited to not more than one year, which will further serve to limit the economic impact of such extensions. The three-week extension of the ADMC Rule's date of effectiveness satisfies this criterion.

For the reasons stated above, the Federal Trade Commission extends the date of effectiveness for the Horseracing Integrity and Safety Authority's Anti-Doping and Medication Control Rule to May 22, 2023.

<sup>3</sup> Compare, e.g., ADMC Rule 4222 (prohibiting all intra-articular injections within fourteen days of post time) with Kentucky Horse Racing Commission Withdrawal Guidelines: Thoroughbred; Standardbred; Quarter Horse, Appaloosa, and Arabian, KHRC 8-020-2 (04/2020) (prohibiting intra-articular injection of specified substances within fourteen days of post time), available at <https://khrc.ky.gov/Documents/8-020-2-Withdrawal%20Guidelines%20%20Copy.pdf>.

<sup>4</sup> 5 U.S.C. 553(b)(3)(B).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* at 553(d).

By direction of the Commission.

**April J. Tabor,**  
Secretary.

[FR Doc. 2023–09247 Filed 5–2–23; 8:45 am]

BILLING CODE 6750–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10174]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by July 3, 2023.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following

address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: \_\_\_\_\_, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786–4669.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

**CMS–10174** Collection of Prescription Drug Data from MA–PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

##### Information Collection

1. *Type of Information Collection Request:* Revision of the currently approved collection; *Title of Information Collection:* Collection of Prescription Drug Data from MA–PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments; *Use:* The PDE data is used in the Payment Reconciliation System to perform the annual Part D payment reconciliation, any PDE data within the Coverage Gap

Phase of the Part D benefit is used for invoicing in the CGDP, and the data are part of the report provided to the Secretary of the Treasury for Section 9008.

The information users will be pharmacy benefit managers (PBMs), third party administrators and pharmacies, and the PDPs, MA–PDs, Fallbacks, and other plans that offer coverage of outpatient prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The statutorily required data is used primarily for payment and is used for claim validation as well as for other legislated functions such as quality monitoring, program integrity and oversight. In addition, the PDE data are used to support operations and program development.

CMS has used PDE data to create summarized dashboards and tools, including the Medicare Part D Drug Spending Dashboard & Data, the Part D Manufacturer Rebate Summary Report, and the Medicare Part D Opioid Prescribing Mapping Tool. The data are also used in the Medicare Trustees Report. Due to the market sensitive nature of PDE data, external uses of the data are subject to significant limitations. However, CMS does analyze the data on a regular basis to determine drug cost and utilization patterns in order to inform programmatic changes and to develop informed policy in the Part D program. *Form Number:* CMS–10174 (OMB control number: 0938–0982); *Frequency:* Monthly; *Affected Public:* Private Sector, Federal Government; *Number of Respondents:* 856; *Total Annual Responses:* 1,499,065,636; *Total Annual Hours:* 62,918. (For policy questions regarding this collection contact Shelly Winston at (443) 934–3621.)

Dated: April 28, 2023.

**William N. Parham, III,**  
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–09398 Filed 5–2–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–N–0623]

#### Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.