■ 4. In appendix H to part 25, section H25.4, add new paragraph (a)(5) to read as follows:

Appendix H to Part 25—Instructions for Continued Airworthiness

* * * * *

H25.4 Airworthiness Limitations section.

(a) * * *

(5) Each mandatory replacement time, inspection interval, and related inspection and test procedure, and each critical design configuration control limitation for each lightning protection feature approved under § 25.954.

* * * * *

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on September 6, 2018.

Carl Burleson,

Acting Deputy Administrator.

[FR Doc. 2018–20174 Filed 9–19–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2017–F–3717]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_3

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulation for vitamin D_3 to replace the current Reference Daily Intake (RDI) percentage values of calcium in 100 percent fruit juices and fruit juice drinks with absolute values and to update the reference for vitamin D_3 specifications. We are taking this action in response to a food additive petition filed by the Juice Products Association.

DATES: This rule is effective September 20, 2018. Submit either electronic or written objections and requests for a hearing on the final rule by October 22, 2018. The Director of the Federal Register approves the incorporation by reference of certain publications listed in the rule as of September 20, 2018. See the **ADDRESSES** section and the OBJECTIONS section IX of this document for further information on filing objections.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before October 22, 2018. The *https://www.regulations.gov* electronic filing system will accept objections until midnight Eastern Time at the end of October 22, 2018. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–F–3717 for ''Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D_3 Final Rule.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1071.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 26, 2017 (82 FR 34615), amended August 22, 2017 (82 FR 39711), we announced that we filed a food additive petition (FAP 7A4818) submitted on behalf of the Juice Products Association by Hogan

Lovells US LLP, Columbia Square, 555 Thirteenth Street NW, Washington, DC 20004. The petition proposed to amend the food additive regulations in § 172.380 (21 CFR 172.380), *Vitamin D_3*, to replace the currently specified minimum RDI percentage values of calcium in calcium-fortified 100 percent fruit juices and fruit juice drinks with absolute values. Specifically, § 172.380(c)(1) currently provides for the use of vitamin D_3 at a level not to exceed 100 International Units (IU) per 240 milliliters (mL) in 100 percent fruit juices that are fortified with greater than or equal to 33 percent of the RDI of calcium per 240 mL, excluding fruit juices that are specifically formulated or processed for infants. In addition, § 172.380(c)(2) provides for the use of up to 100 IU of vitamin D_3 per 240 mL in fruit juice drinks that are fortified with greater than or equal to 10 percent of the RDI of calcium per 240 mL, excluding fruit juice drinks that are specifically formulated or processed for infants. The petitioner proposed to replace the RDI percentage values of calcium in 100 percent fruit juices and fruit juice drinks in these regulations with the absolute values of added calcium of 330 milligrams (mg) and 100 mg per 240 mL, respectively. The petitioner also requested that we update the reference for specifications for vitamin D_3 in § 172.380(b) from the 9th edition of the Food Chemicals Codex (FCC 9) to the 10th edition (FCC 10).

II. Evaluation of Petition

Section 409(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(i)) states that we shall, by regulation, establish the procedure for amending or repealing a food additive regulation, and that this procedure shall conform to the procedure provided in section 409 of the FD&C Act. Our regulations specific to administrative actions for food additives provide that the Commissioner of Food and Drugs, on his own initiative or on the petition of any interested person, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive (§ 171.130(a) (21 CFR 171.130(a))). The regulations further provide that any such petition must include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data submitted as a food additive petition must be furnished in the form specified in 21 CFR 171.1 and 171.100 for submitting such petitions (§ 171.130(b)).

In the **Federal Register** of February 27, 2003 (68 FR 9000), we issued the regulations at § 172.380(c)(1) and (2) permitting the use of vitamin D_3 in calcium fortified 100 percent fruit juices and fruit juice drinks. We took that action in response to a food additive petition (FAP 2A4734) from the Minute Maid Co. (Minute Maid). Minute Maid petitioned for vitamin D_3 to be allowed to be added to calcium-fortified 100 percent fruit juices and fruit juice drinks so that the calcium and vitamin D levels are comparable to the levels in milk. When we issued these regulations in 2003, the RDI for calcium was 1,000 mg; however, in the **Federal Register** of May 27, 2016 (81 FR 33742), we issued a final rule which, among other things, redefined the RDI of calcium for adults and children 4 years of age and older to 1,300 mg (21 CFR 101.9(c)(8)(iv)). Because of the change in the RDI for calcium, the minimum level of added calcium in 100 percent fruit juice that may be fortified with vitamin D_3 increased from 330 mg to 430 mg and in fruit juice drinks from 100 mg to 130 mg.

The Juice Products Association stated that the proposed revision of § 172.380 to specify absolute values of calcium on a mg/mL basis rather than a percentage of RDI is needed to maintain the relative parity between fortified 100 percent fruit juices and fruit juice drinks and many dairy products. Without this change, the petitioner stated that 100 percent fruit juices with vitamin D_3 would have higher calcium levels than milk. The petitioner also stated that the higher levels of calcium resulting from the redefined RDI for calcium present formulation challenges and may adversely impact the taste of the juice or juice drink, which could deter consumers from selecting calcium and vitamin D fortified juices. Therefore, the petitioner proposed that § 172.380 be amended to express the allowable added calcium levels on a mg basis consistent with the calcium levels before the revision of the RDI for calcium. In doing so, the allowable levels of calcium and vitamin D in 100 percent fruit juices and juice drinks would again be comparable to the levels in milk.

Because the petitioner sought to revise the existing regulation to restore the amount of calcium fortification required to levels on par with milk, without introducing new uses for vitamin D_3 or changing the levels of vitamin D_3 and calcium that were considered when the regulations were established, there is no increase in dietary exposure to vitamin D_3 or to calcium. Therefore, we have determined that there are no safety concerns as a result of the proposed amendment.

Additionally, the current regulation for the use of vitamin D_3 in food (§ 172.380) indicates that the additive must meet the specifications in the 9th edition of the Food Chemicals Codex (FCC 9). The petitioner requested that we update the specifications for vitamin D_3 in § 172.380 by replacing the existing FCC 9 reference with the 10th edition of the Food Chemicals Codex (FCC 10), the most recent edition at the time the petition was submitted. The specifications for vitamin D_3 in FCC 10 are identical to those in FCC 9. However, since we received the petition, FCC has been updated to the 11th edition (FCC 11). The specifications for vitamin D_3 in FCC 11 are identical to those in FCC 10. Therefore, we are amending § 172.380 by adopting the specifications for vitamin D_3 in FCC 11 in place of FCC 9, because FCC 11 is the most current version.

III. Incorporation by Reference

FDA is incorporating by reference the monograph from Food Chemicals Codex, 11th ed., 2018, pp. 1243–1244 (vitamin D_3), which is approved by the Director of the Office of the Federal Register. You may purchase a copy of the material from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852, 1–800–227–8772, *http://www.usp.org/.* Copies also may be examined at FDA's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039.

The FCC monograph establishes the standard for purity and identity for vitamin D_3. The monograph provides specifications and analytical methodologies used to identify the substance and establish acceptable purity criteria. To ensure that only food grade vitamin D_3 is used in foods listed in § 172.380, the additive must meet the specifications and identity in the FCC monograph.

IV. Conclusion

Based on data and information in the petition, we conclude that amending the food additive regulations in the regulation for vitamin D_3 to replace the current RDI percentage values of calcium in 100 percent fruit juices and fruit juice drinks with absolute values is safe and appropriate. Thus, the RDI percentage values of calcium in 100 percent fruit juices and fruit juice drinks in these regulations are replaced with the absolute values of added calcium of

330 mg and 100 mg per 240 mL, respectively. Consequently, we are amending the food additive regulations as set forth in this document.

Additionally, the current regulation for the use of vitamin D_3 in food (§ 172.380) indicates that the additive must meet the specifications in FCC 9. The more current version is FCC 11, which contains specifications for vitamin D_3 that are identical to those in FCC 9. We are amending § 172.380 by adopting the specifications for vitamin D_3 in FCC 11 in place of FCC 9.

V. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

VI. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the July 26, 2017, **Federal Register** notice of filing (82 FR 34615). We stated in the notice of filing that we had determined, under 21 CFR 25.30(i), that this action ''is of a type that does not individually or cumulatively have a significant effect on the human environment because the amendments are administrative in nature'' such that neither an environmental assessment nor an environmental impact statement is required. Upon further consideration, we determined that FAP 7A4818 is not solely administrative in nature as this revision has the potential to lead to manufacturing changes. Consequently, the action being requested is neither a correction nor technical change and the original categorical exclusion (21 CFR 25.30(i)) is not appropriate. Therefore, we have determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment because the added vitamin D_3 and calcium will remain in the fruit juice and fruit juice drinks through ingestion by consumers and neither food additive is intended to replace macronutrients. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

Our review of this petition was limited to section 409 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

IX. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Amend § 172.380 by revising paragraphs (b) and (c)(1) through (2) to read as follows:

§ 172.380 Vitamin D_3.

* * * * *

(b) Vitamin D_3 meets the specifications of ''Vitamin D_3,'', Food Chemicals Codex, 11th ed., copyright 2018, pp. 1243–1244, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(c) * * *

(1) At levels not to exceed 100 International Units (IU) per 240 milliliters (mL) in 100 percent fruit juices (as defined under § 170.3(n)(35) of this chapter) that are fortified with greater than or equal to 330 milligrams (mg) of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.

(2) At levels not to exceed 100 IU per 240 mL in fruit juice drinks (as defined under § 170.3(n)(35) of this chapter) that

are fortified with greater than or equal to 100 mg of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.

* * * * *

Dated: September 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20375 Filed 9–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0273]

RIN 1625–AA09

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Palm Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the operating schedule that governs the operation of the Flagler Memorial (SR A1A) Bridge, mile 1021.8, the Royal Park (SR 704) Bridge, mile 1022.6, and the Southern Boulevard (SR 700/80) Bridge, mile 1024.7, across the Atlantic Intracoastal Waterway, at West Palm Beach, Florida. This modification allows the Flagler Memorial, Royal Park and Southern Boulevard Bridges to operate on alternative schedules when the President of the United States, members of the First Family, or other persons under the protection of the Secret Service visit Mar-a-Lago. The modifications are necessary to accommodate the increase in vehicular traffic when the presidential motorcade is in transit.

DATES: This rule is effective on September 20, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov.* Type USCG–2017–0273 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email CWO4 Robert Wooten, Coast Guard Sector Miami, FL, Waterways Management Division, telephone 305–535–4311, email *robert.a.wooten@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of proposed rulemaking (Advance, Supplemental)
§ Section
U.S.C. United States Code
FL Florida
FDOT Florida Department of Transportation
AICW Atlantic Intracoastal Waterway

II. Background Information and Regulatory History

On August 17, 2017, the Coast Guard published a notice of deviation from drawbridge regulation with request for comments in the **Federal Register** (82 FR 39019) to test proposed changes. Three comments were received. Due to delays in processing this proposed regulatory change, on March 6, 2018, the Coast Guard published a notice of deviation from regulations with request for comments extension in the **Federal Register** (82 FR 9431) to allow for additional time for the public to comment. One comment was received. On May 21, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Palm Beach, FL in the **Federal Register** (83 FR 23398). No comments were received. Due to delays in processing this regulatory change, on June 25, 2018, the Coast Guard published a notice of deviation from regulations with request for comments extension in the **Federal Register** (83 FR 29438) to allow additional time for public comment and to evaluate the changes to the operating schedules with the establishment of the Presidential Security Zone (82 FR 17295). No comments were received.

We are issuing rule under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. The notice of deviation published in the **Federal Register** (83 FR 29438) expires on August 29, 2018 and this rule must be in effect immediately thereafter.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499. The Flagler Memorial (SR A1A) Bridge, mile 1021.8, across the AICW (Lake Worth Lagoon) at West Palm Beach, Florida is a double-leaf bascule bridge that has a vertical clearance of 22 feet at mean high water in the closed position. The Royal Park (SR 704) Bridge, mile 1022.6, across the AICW (Lake Worth Lagoon) at West Palm Beach, Florida is a double-leaf bascule bridge that has a vertical clearance of 21 feet at mean high water in the closed position. The Southern Boulevard (SR 700/80) Bridge, mile 1024.7, across the AICW (Lake Worth Lagoon) at West Palm Beach, Florida is under construction, a temporary lift bridge is in place that has a vertical clearance of 14 feet at mean high water in the closed position and a 65 foot vertical clearance in the open position. The existing regulations are published in 33 CFR 117.261(u), Flagler Memorial Bridge, § 117.261(v) Royal Park Bridge, and § 117.261(w) Southern Boulevard Bridge.

The bridge owner, Florida Department of Transportation, requested changes to the drawbridge operating schedules to better facilitate orderly vehicle traffic flow across the Flagler Memorial, Royal Park and Southern Boulevard bridges when the President of the United States, members of the First Family, or other persons under the protection of the Secret Service visit Mar-a-Lago. The increase in traffic congestion occurs when the Presidential Security Zone (82 FR 17295) is enforced which closes the Southern Boulevard Bridge when the presidential motorcade is in transit. This action requires through traffic to use the Flagler Memorial and Royal Park Bridges.

IV. Discussion of Comments, Changes and the Final Rule

As noted above, we received four comments total on the two notices of deviation published on August 17, 2017 and March 6, 2018, respectively. Of the four comments received, one was a political statement with no relevance on the proposed regulation. Three of the four comments received were in favor of the regulation. Two of the comments in favor of the regulation suggested the changes be made permanent regardless of presidential visits. The Coast Guard has considered this recommendation, however, making the modified operating schedule permanent would place an unreasonable burden on navigation and potentially have a negative impact on safe navigation. The modified schedule is only in effect when uninterrupted transit of dignitaries are crossing the Southern Boulevard Bridge. While vessels may have to wait up to an hour, it is only during the weekdays and for a short period.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and