

## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Chapter II

[Release Nos. 33–11252; 34–98699; IA–6454; IC–35030; File No. S7–17–23]

### List of Rules To Be Reviewed Pursuant to the Regulatory Flexibility Act

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Publication of list of rules scheduled for review.

**SUMMARY:** The Regulatory Flexibility Act (“RFA”) requires an agency to publish in the **Federal Register**, each year, a list of rules that are to be reviewed in accordance with the RFA during the succeeding 12 months. Based upon its review of rules potentially subject to review under the RFA during the succeeding 12 months, the Securities and Exchange Commission (“Commission”) has determined that no such rules are required to be reviewed. Accordingly, the agency is not publishing a list of rules to be reviewed pursuant to the RFA during the succeeding 12 months.

**DATES:** October 13, 2023.

#### FOR FURTHER INFORMATION CONTACT:

Sandra Sojka, General Attorney, Office of the General Counsel, 202–551–4928.

**SUPPLEMENTARY INFORMATION:** The Regulatory Flexibility Act (“RFA”), codified at 5 U.S.C. 601 through 612, requires an agency to review its rules that have a significant economic impact upon a substantial number of small entities within 10 years of the publication of such rules as final rules. 5 U.S.C. 610(a). The purpose of the review is “to determine whether such rules should be continued without change, or should be amended or rescinded . . . to minimize any significant economic impact of the rules upon a substantial number of such small entities.” 5 U.S.C. 610(a).

The RFA further requires an agency to publish in the **Federal Register**, each year, a list of the rules that are to be reviewed in accordance with the RFA during the succeeding 12 months. 5 U.S.C. 610(c). In determining which rules to include in each year’s rule review list, the Commission analyzes rules adopted in the ninth calendar year prior to the year the rule review list is published, and those rules included in the rule review list are reviewed in accordance with the RFA during the calendar year following the year the rule review list is published. The Commission includes in its rule review lists any rules that may have a

significant economic impact on a substantial number of small entities, but excludes rules that previously have been reviewed, rules that have been substantially changed since adoption, rules that are minor amendments to previously adopted rules, and rules that are ministerial, procedural, or technical in nature. Based upon an analysis of the rules adopted by the Commission in 2014, the Commission has determined that no such rules are required to be reviewed pursuant to the RFA during the succeeding 12 months. Accordingly, the agency is publishing a list that reflects that there are no rules to be reviewed pursuant to the RFA during the succeeding 12 months.

By the Commission.

Dated: October 6, 2023.

**J. Lynn Taylor,**

*Assistant Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 172

[Docket No. FDA–2023–F–4332]

### Kerry Ingredients and Flavours Ltd.; Filing of Food Additive Petition

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

**ACTION:** Notification of petition.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Kerry Ingredients and Flavours Ltd., proposing that the food additive regulations be amended to provide for the safe use of vitamin D<sub>3</sub> as a nutrient supplement in powdered drink mixes added to water or carbonated water, excluding drinks or drink mixes that are specially formulated or processed for infants.

**DATES:** The food additive petition was filed on April 26, 2023.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this 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:** Lane A. Highbarger, Center for Food

Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1204.

**SUPPLEMENTARY INFORMATION:** Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 2A4834), submitted on behalf of Kerry Ingredients and Flavours Ltd. by Hogan Lovells US LLP, Columbia Square, 555 13th Street NW, Washington, DC 20004. The petition proposes to amend the food additive regulations in 21 CFR 172.380 “Vitamin D<sub>3</sub>,” to provide for the safe use of vitamin D<sub>3</sub> as a nutrient supplement in powdered drink mixes added to water or carbonated water at levels not to exceed 180 international units per 360 milliliters (mL) as consumed, excluding drinks or drink mixes that are specially formulated or processed for infants (Refs. 1 and 2). If calcium is added, calcium is present at levels greater than or equal to 150 milligrams of calcium per 360 mL as consumed (Refs. 1 and 2).

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(k) because the substance is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist that would warrant an environmental assessment (see 21 CFR 25.21). If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

#### References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Emails from M. Gradison, to L. Highbarger, March 8, 2023, and March 30, 2023.
2. FDA Memorandum from L. Highbarger, Regulatory Review Branch, March 30, 2023.