

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 172

[Docket No. FDA-2017-F-3717]

#### Juice Products Association; Filing of Food Additive Petition

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

**ACTION:** Notification; petition for rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by the Juice Products Association, proposing that the food additive regulations be amended to replace the current Recommended Daily Intake (RDI) percentage values of calcium in fruit juices and fruit juice drinks in the regulation for vitamin D<sub>3</sub> with absolute values and to update the specifications for vitamin D<sub>3</sub>.

**DATES:** The food additive petition was filed on June 1, 2017.

**ADDRESSES:** For access to the docket, 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, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1071.

**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 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 proposes to amend the food additive regulations in

§ 172.380 (21 CFR 172.380) *Vitamin D<sub>3</sub>* by replacing the current RDI percentage values of calcium in fruit juices and fruit juice drinks specified in § 172.380(c)(1) and (2) with absolute values and to update the specifications for vitamin D<sub>3</sub> established in § 172.380(b) by incorporating by reference the most recent edition of the Food Chemicals Codex.

These proposed changes would allow manufacturers of fruit juices and fruit juice drinks that are fortified with calcium to maintain the absolute level of added calcium at 330 milligrams (mg) and 130 mg, respectively, as established in our regulations at § 172.380(c)(1) and (2).

We have 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 and permit manufacturers of fruit juices and fruit juice drinks that are fortified with calcium to maintain current calcium fortification levels in these products. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: July 19, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-15535 Filed 7-25-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 573

[Docket No. FDA-2017-F-4125]

#### Zinpro Corp.; Filing of Food Additive Petition (Animal Use)

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

**ACTION:** Notification; petition for rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that Zinpro Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of zinc-L-selenomethionine as a nutritional

source of selenium in complete feed for laying hens and for the safe use of the approved food additive silicon dioxide as an anticaking agent for use with zinc-L-selenomethionine as a feed component.

**DATES:** The food additive petition was filed on June 1, 2017.

**ADDRESSES:** For access to the docket, 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:** Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6729, [chelsea.trull@fda.hhs.gov](mailto:chelsea.trull@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2303) has been filed by Zinpro Corp., 10400 Viking Dr., Suite 240, Eden Prairie, MN 55344. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 (21 CFR part 573) *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of zinc-L-selenomethionine as a nutritional source of selenium in complete feed for laying hens and for the safe use of silicon dioxide (21 CFR 573.940) as an anticaking agent for use with zinc-L-selenomethionine as a feed component.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(r) because it is of a type that does not individually or cumulatively have a significant effect on the human environment. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist. 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.