



4164-01-P

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 D₃ with absolute values and to update the specifications for vitamin D₃.

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 D₃ 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 D₃ 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.

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