4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2021-F-1157]

Lallemand Inc.; 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 Lallemand Inc., proposing that the food additive regulations be amended to provide for the safe use of vitamin D_2 heat-killed ("inactive") baker's yeast as a source of vitamin D_2 in specific food categories.

DATES: The food additive petition was filed on September 28, 2021.

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: Katie Overbey, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-7536.

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 1A4829), submitted by Lallemand Inc., 1620 rue Prefontaine, Montreal, Quebec, H1W 2N8, Canada. The petition proposes to amend the food additive regulations in 21 CFR part 172, *Food additives permitted for direct addition to food for human consumption*, to allow for the safe use of vitamin D_2 heat-killed bakers yeast as a nutrient supplement in foods to which

vitamin D_2 mushroom powder is currently allowed to be added under § 172.382 (21 CFR 172.382), at the maximum level of vitamin D_2 authorized under § 172.382.

The petitioner has claimed a categorical exclusion 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 at least 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.

Dated: December 21, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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