4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2021-F-0926]

Monaghan Mushrooms Ireland Unlimited Company; 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 Monaghan Mushrooms Ireland Unlimited Company, proposing that the food additive regulations be amended to provide for the safe use of vitamin D_2 mushroom powder produced by exposing dried and powdered edible cultivars of *Agaricus bisporus* to ultraviolet light.

DATES: The food additive petition was filed on June 8, 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 the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food

additive petition (FAP 1A4828), submitted by Monaghan Mushrooms Ireland Unlimited Company, Tullygony, Tyholland, County Monaghan, H18 FW95, Ireland. The petition proposes to amend the food additive regulations in § 172.382 (21 CFR 172.382) *Vitamin D_2 mushroom powder* to provide for the safe use of vitamin D_2 mushroom powder produced by exposing dried and powdered edible cultivars of *Agaricus bisporus* to ultraviolet light.

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 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: September 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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