4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. FDA-2026-F-6436]

Sterigenics U.S., LLC; 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 food additive petition, submitted by Sterigenics U.S., LLC, proposing that we amend our food additive regulations to provide for the safe use of ionizing radiation for the reduction of pathogens in raw enriched wheat flour.

DATES: The food additive petition was filed on June 5, 2026.

ADDRESSES: For access to the docket to read background documents, 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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2710.

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 6M4844), submitted on behalf of Sterigenics U.S., LLC, by the Burdock Group, P.O. Box 780519, Orlando, FL 32878. The petition proposes that we amend our food additive regulations in § 179.26 (21 CFR 179.26), "Ionizing Radiation for the Treatment of Food," to provide for the safe use of ionizing radiation for the reduction of pathogens in raw enriched wheat flour, at a level not to exceed 30 kiloGray (kGy).

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(j), because the granting of this petition would authorize the use of substances used as a component of a food-contact surface of permanent or semi-permanent equipment or of another food-contact article intended for repeated use. 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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