4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2025-F-3179]

Biomin GmbH; Filing of Food Additive Petition (Animal Use)

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 Biomin GmbH, proposing that we amend our food additive regulations to provide for the safe use of zearalenone hydrolase to degrade zearalenone in swine food at no less than 10 U/kg complete feed (U = the five-fold enzymatic activity that hydrolyzes 1 µmol zearalenone per minute in a solution of 5 mg/L zearalenone).

DATES: The food additive petition was filed on August 6, 2025.

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: Lauren Howell, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240-402-8012, Lauren.Howell@fda.hhs.gov.

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 2324), submitted by Biomin GmbH, Erber Campus 1, 3131 Getzersdorf, Austria. The petition proposes that we amend our food additive regulations in 21 CFR part 573--Food Additives Permitted in Feed and Drinking Water of Animals, to provide for the safe use of

Zearalenone hydrolase to degrade zearalenone in swine food at no less than 10 U/kg complete feed (U = the five-fold enzymatic activity that hydrolyzes 1 μmol zearalenone per minute in a solution of 5 mg/L zearalenone).

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 that may significantly affect the quality of the human environment. 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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