



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2020-F-1275]

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

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 Biomin GmbH, proposing that the food additive regulations be amended to provide for the safe use of fumonisin esterase to degrade fumonisins present in swine feed.

DATES: The food additive petition was filed on March 26, 2020.

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: Carissa Adams, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6283, [Carissa.Adams@fda.hhs.gov](mailto:Carissa.Adams@fda.hhs.gov).

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 2311) submitted by Biomin GmbH; Erber Campus 1, 3131 Getzersdorf, Austria. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573

(21 CFR part 573) *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of fumonisin esterase to degrade fumonisins present in swine feed.

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. 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.

Date: April 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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