



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2015-F-2337]

Alzchem AG; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Alzchem AG has filed a petition proposing that the food additive regulations be amended to provide for the safe use of guanidinoacetic acid as a substance that spares arginine and serves as a precursor of creatine in diets for broiler chickens and turkeys.

DATES: Submit either electronic or written comments on the petitioner's request for categorical exclusion from preparing an environmental assessment or environmental impact statement by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to: <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6729.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 2292) has been filed by Alzchem AG, Chemiepark Trostberg, Dr.-Albert-Frank-Str. 32, 83308, Trostberg, Germany. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 Food Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573) to provide for the safe use of guanidinoacetic acid as a substance that spares arginine and serves as a precursor of creatine in diets for broiler chickens and turkeys. The petitioner has requested a categorical exclusion from preparing an environmental assessment or environmental impact statement under 21 CFR 25.32(r).

Interested persons may submit either electronic or written comments regarding this request for categorical exclusion to the Division of Dockets Management (see DATES and ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: July 10, 2015.

William T. Flynn,

Acting Director,

Center for Veterinary Medicine

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