4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2019-F-5401]

Alzchem Trostberg 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 Alzchem Trostberg GmbH has filed a petition proposing that the food additive regulations be amended to provide for the safe use of guanidinoacetic acid as a precursor of creatine in poultry feeds.

DATES: The food additive petition was filed on September 25, 2019.

ADDRESSES: For access to the docket, 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.

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 2309) has been filed by Alzchem Trostberg GmbH, 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 (21 CFR part 573) *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of guanidinoacetic acid as a precursor of creatine in poultry feeds.

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.

Dated: November 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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