4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

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

Food Additives Permitted in Feed and Drinking Water of Animals; Guanidinoacetic Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of guanidinoacetic acid as a substance that spares arginine and serves as a precursor of creatine in broiler chicken and turkey feeds. This action is in response to a food additive petition filed by Alzchem AG.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either written or electronic objections and requests for a hearing by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section V of this document for information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows:

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your

objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on http://www.regulations.gov.

- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Division of Dockets Management, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-F-2337 for "Food Additives Permitted in Feed and Drinking Water of Animals; Guanidinoacetic Acid." Received objections will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies in total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of objections. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your objections and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper objections received, go to http://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 Division of Dockets Management, 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, chelsea.trull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the Federal Register of July 16, 2015 (80 FR 42069), FDA announced that we had filed a food additive petition (animal use) (FAP 2292) submitted by Alzchem AG, Chemiepark Trostberg, Dr.-Albert-Frank-Str. 32, 83308, Trostberg, Germany. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals 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 broiler chicken and turkey feeds. The notice of petition provided for a 30-day comment period on the petitioner's request for categorical exclusion from preparing an environmental assessment or environmental impact statement.

II. Conclusion

FDA concludes that the data establish the safety and utility of guanidinoacetic acid for use as a substance that spares arginine and serves as a precursor of creatine in broiler chicken and turkey feeds and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection.

Any objections received in response to the regulation 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.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Add § 573.496 to read as follows:

§ 573.496 Guanidinoacetic acid.

The food additive, guanidinoacetic acid, may be safely used in broiler chicken and turkey feeds in accordance with the following prescribed conditions:

(a) The additive is manufactured by reacting glycine with cyanamide in an aqueous solution.

(b) The additive is used or intended for use to spare arginine and as a precursor of creatine in broiler chicken and turkey feeds at levels not to exceed 0.12 percent of the complete feed.

(c) The additive consists of not less than 97 percent guanidinoacetic acid [N--(aminoiminomethyl)-glycine] (CAS 352-97-6) by weight.

(d) The additive meets the following specifications:

(1) Dicyandiamide not to exceed 0.5 percent;

(2) Cyanamide not to exceed 0.01 percent;

(3) Melamine not to exceed 15 parts per million (ppm);

(4) Sum of ammeline, ammelide, and cyanuric acid not to exceed 35 ppm; and

(5) Water not to exceed 1 percent.

(e) To assure safe use of the additive in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed shall contain the name of the additive.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) A statement to indicate that the maximum use level of guanidinoacetic acid must not exceed 0.12 percent of the complete feed for broiler chickens and turkeys; and

(ii) Adequate directions for use.

Dated: November 22, 2016.

Tracey H. Forfa,

Deputy Director,

Center for Veterinary Medicine.

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