§ 1026.3(b) exemption at consummation in year one is refinanced in year ten and that the new loan amount is less than the threshold amount in effect in year ten. In these circumstances, the creditor must comply with all of the applicable requirements of this part with respect to the year ten transaction if the original loan is satisfied and replaced by the new loan, which is not exempt under § 1026.3(b). See also comment 3(b)–6.

6. Addition of a security interest in real property or a dwelling after account opening or consumption. i. Open-end credit. For open-end accounts, if after account opening a security interest is taken in real property, or in personal property used or expected to be used as the consumer’s principal dwelling, a previously exempt account ceases to be exempt under § 1026.3(b) and the creditor must begin to comply with all of the applicable requirements of this part within a reasonable period of time. See comment 3(b)–4. ii. If a security interest is taken in the consumer’s principal dwelling, the creditor must also give the consumer the right to rescind the security interest consistent with § 1026.15.

ii. Closed-end credit. For closed-end loans, if after consummation a security interest is taken in real property, or in personal property used or expected to be used as the consumer’s principal dwelling, an exempt loan remains exempt under § 1026.3(b). However, the addition of a security interest in the consumer’s principal dwelling is a transaction for purposes of § 1026.23, and the creditor must give the consumer the right to rescind the security interest consistent with that section. See § 1026.23(a)(1) and its commentary. In contrast, if a closed-end loan that is exempt under § 1026.3(b) is satisfied and replaced by a loan that is secured by real property, or by personal property used or expected to be used as the consumer’s principal dwelling, the new loan is not exempt under § 1026.3(b), and the creditor must comply with all of the applicable requirements of this part. See comment 3(b)–5.

7. Application to extensions secured by mobile homes. Because a mobile home can be a dwelling under § 1026.2(a)(19), the exemption in § 1026.3(b) does not apply to a credit extension secured by a mobile home that is used or expected to be used as the principal dwelling of the consumer. See comment 3(b)–6.

8. Transition rule for open-end accounts exempt prior to July 21, 2011. Section 1026.3(b)(2) applies only to open-end accounts opened prior to July 21, 2011. Section 1026.3(b)(2) does not apply if a security interest is taken by the creditor in real property, or in personal property used or expected to be used as the consumer’s principal dwelling. If, on July 20, 2011, an open-end account is exempt under § 1026.3(b) based on a firm commitment to extend credit in excess of $25,000, the account remains exempt under § 1026.3(b)(2) until December 31, 2011 (unless the firm commitment is reduced to $25,000 or less). If the firm commitment is increased on or before December 31, 2011 to an amount in excess of $50,000, the account remains exempt under § 1026.3(b)(1) regardless of subsequent increases in the threshold amount as a result of increases in the CPI–W. If the firm commitment is not increased on or before December 31, 2011 to an amount in excess of $50,000, the account ceases to be exempt under § 1026.3(b) based on a firm commitment to extend credit. For example:

i. Assume that, on July 20, 2011, the account is exempt under § 1026.3(b) based on the creditor’s firm commitment to extend $30,000 in credit. On November 1, 2011, the creditor increases the firm commitment on the account to $55,000. In these circumstances, the account remains exempt under § 1026.3(b)(1) regardless of subsequent increases in the threshold amount as a result of increases in the CPI–W.

ii. Same facts as paragraph i above except, on November 1, 2011, the creditor increases the firm commitment on the account to $40,000. In these circumstances, the account ceases to be exempt under § 1026.3(b)(2) after December 31, 2011, and the creditor must begin to comply with the applicable requirements of this part.

By order of the Board of Governors of the Federal Reserve System, November 17, 2016.

Robert DeV. Frierson,
Secretary of the Board.
Dated: November 7, 2016.

Richard Cordray,
Director, Bureau of Consumer Financial Protection.

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 November 30, 2016. Submit either written or electronic objections and requests for a hearing by December 30, 2016. 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 docket, 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 review this copy, including the claimed confidentiality, in its entirety. The petition was considered and relied upon in reaching our decision to approve the petition. See § 573.496 Guanidinoacetic acid.

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.

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

§ 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 glyicine 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 feed at levels not to exceed 0.12 percent of the complete feed.

(c) The additive consists of not less than 97 percent guanidinobaciteic 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 guanidinobaciteic 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.