4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket Nos. FDA-2013-F-1540 and FDA-2014-F-0296]

Food Additives Permitted in Feed and Drinking Water of Animals; 25-Hydroxyvitamin D_3

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of 25-hydroxyvitamin D_3 as a source of vitamin D_3 activity for layer and breeder chickens and turkeys. This action is in response to two food additive petitions filed by DSM Nutritional Products.

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

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER

DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting objections. Objections submitted electronically, including attachments, to https://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 https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper objections submitted to the Dockets Management Staff, 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-2013-F-1540 (for submissions related to FAP 2277) or FDA-2014-F-0296 (for submissions related to FAP 2279) for "Food Additives Permitted in Feed and Drinking Water of Animals; 25-hydroxyvitamin D_3." Received objections, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff 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 https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper objections received, go to https://www.regulations.gov and insert the appropriate 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 Doody, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV-228), Rockville, MD 20855, 240-402-6283, carissa.doody@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In documents published in the *Federal Register* of December 23, 2013 (78 FR 77384) and March 26, 2014 (79 FR 16698), FDA announced that we had filed two food additive petitions (animal use) (FAPs 2277 and 2279) submitted by DSM Nutritional Products, 45 Waterview Blvd., Parsippany, NJ 07054. The petitions proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of 25-hydroxyvitamin D_3 as a source of vitamin D_3 activity for layer and breeder chickens (FAP 2277) and turkeys (FAP 2279).

II. Conclusion

FDA concludes that the data establish the safety and utility of 25-hydroxyvitamin D_3 as a source of vitamin D_3 activity for layer and breeder chickens and turkeys and that the food

additive regulations should be amended as set forth in this document. This is not a significant regulatory action subject to Executive Order 12866.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petitions and documents we considered and relied upon in reaching our decision to approve the petitions 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.

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 Dockets Management Staff (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.

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, 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 § 573.550 to subpart B to read as follows:

§ 573.550 25-hydroxyvitamin D_3

The food additive, 25-hydroxyvitamin D_3, may be safely used in accordance with the following prescribed conditions:

(a) The additive is used or intended for use as a source of vitamin D_3 activity in animal feed or drinking water in accordance with good manufacturing and feeding practices as follows:

(1) In feed or drinking water of layer and breeder chickens not to exceed 69 parts per billion (ppb) in feed or 34.5 ppb in drinking water.

(2) In feed or drinking water of turkeys not to exceed:

(i) 92 ppb in feed; or

(ii) In drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.

(b) The additive consists of not less than 94 percent 25-hydroxyvitamin D_3 (9,10-secocholesta-5,7,10(19)-triene-3β, 25-diol).

(c) The additive meets the following specifications:

(1) Not more than 1 percent of any individual sterol.

(2) Not more than 5 percent water.

(3) Not more than 20 parts per million (ppm) lead.

(4) Not more than 20 ppm aluminum.

(5) Not more than 1.0 percent solvents and non-detectable levels of 2', 4', 5', 7' tetraiodofluorescin.

(6) Not more than 1 ppb 1, 25-dihydroxycholecalciferol.

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

(1) The name of the additive.

(2) A statement to indicate the maximum use level of 25-hydroxyvitamin D_3 must not exceed 69 ppb in feed or 34.5 ppb in drinking water for layer and breeder chickens.

(3) A statement to indicate for turkeys the maximum use level of 25-hydroxyvitamin D_3 must not exceed 92 ppb in feed; or in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.

(4) Adequate use directions to ensure that 25-hydroxyvitamin D_3 (and all premixes) is uniformly blended throughout the feed or drinking water.

(5) An expiration date on all premix labeling.

(6) A statement on all premix labeling (feed and drinking water forms) that 25-hydroxyvitamin D_3 cannot be used simultaneously in both feed and water.

Dated: September 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-21396 Filed: 10/1/2018 8:45 am; Publication Date: 10/2/2018]