



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2014-F-1509]

Food Additives Permitted in Feed and Drinking Water of Animals; Marine Microalgae

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 dried marine microalgae as a source of docosahexaenoic acid (DHA) for use in complete, dry foods for adult dogs. This action is in response to a food additive petition 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 midnight 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-2014-F-1509 for "Food Additives Permitted in Feed and Drinking Water of Animals; Marine Microalgae." 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 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: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV-224), Rockville, MD 20855, 240-402-6729, chelsea.trull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the *Federal Register* of October 16, 2014 (79 FR 62090), FDA announced that we had filed a food additive petition (animal use) (FAP 2288) submitted by DSM Nutritional Products, 45 Waterview Blvd., Parsippany, NJ 07054. 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 *Schizochytrium* sp. dried marine microalgae as a source of DHA for use in complete, dry foods for adult dogs.

II. Conclusion

FDA concludes that the data establish the safety and utility of *Schizochytrium* sp. dried marine microalgae as a source of DHA for use in complete, dry foods for adult dogs 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 petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for inspection at the Center for Veterinary Medicine by appointment with the information contact person (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 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 § 573.615 to subpart B to read as follows:

§ 573.615 Marine microalgae.

The food additive, marine microalgae, may be safely used as a source of docosahexaenoic acid (DHA) and other omega-3 fatty acids in accordance with the following prescribed conditions:

(a) The additive is dried whole cells of nonviable, nontoxigenic, nonpathogenic *Schizochytrium* sp. algae grown as a pure culture.

(b) The additive is used in complete, dry adult maintenance food for dogs in accordance with good manufacturing and feeding practices not to exceed 16.5 pounds per ton (7.5 kilograms (kg) per 1000 kg) of complete, dry, adult maintenance dog food.

(c) The additive consists of not less than 17.0 percent (4Z,7Z,10Z,13Z,16Z,19Z)-docosa-4,7,10,13,16,19-hexaenoic acid (docosahexaenoic acid or DHA).

(d) The additive meets the following specifications:

(1) Not less than 40 percent crude fat;

(2) Not more than 12 percent ash;

(3) Not more than 8 percent unsaponifiable matter;

(4) Not more than 5 percent insoluble impurities;

(5) Not more than 5 percent free fatty acids; and

(6) Not more than 6 percent water.

(e) To ensure the safe use of the additive, in addition to 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, marine microalgae.

(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 the additive shall not exceed 16.5 pounds per ton (7.5 kg per 1000 kg) of complete, dry, adult maintenance dog food.

(ii) Adequate directions for use.

Dated: May 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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