4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2012-F-0949]

Food Additives Permitted in Feed and Drinking Water of Animals; Gamma-Linolenic Acid Safflower Oil

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or 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 oil from a variety of bioengineered safflower as a source of omega-6 fatty acids in complete dry adult maintenance dog food. This action is in response to a food additive petition filed by Arcadia Biosciences, Inc.

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 the ADDRESSES section, and SUPPLEMENTARY INFORMATION section V of this document, for further information on the filing of objections.

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

objections 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-2012-F-0949 for "Food Additives Permitted in Feed and Drinking Water of Animals; Gamma-Linolenic Acid Safflower Oil." 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., Rockville, MD 20855, 240-402-6729, chelsea.trull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of September 12, 2012 (77 FR 56175), FDA announced that we had filed a food additive petition (animal use) (FAP 2275) submitted by Arcadia Biosciences, Inc., 202 Cousteau Pl., suite 200, Davis, CA 95618. 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 oil from a variety of bioengineered safflower (Carthamus tinctorius L.) in complete dry adult maintenance dog food. The safflower variety has been bioengineered to contain a gene from the water mold Saprolegnia diclina responsible for

production of gamma-linolenic acid (GLA) in the seed oil. This GLA-enriched safflower oil will be used as a source of omega-6 fatty acids in dry food for adult dogs. 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 GLA safflower oil as a source of omega-6 fatty acids in complete dry adult maintenance dog food 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 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. 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.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at https://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, 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 § 573.492 to read as follows:

§ 573.492 Gamma-linolenic acid safflower oil.

The food additive gamma-linolenic acid (all-cis-6,9,12-octadecatrienoic acid) (GLA) safflower oil contains an omega-6 fatty acid that may be safely used in animal food in accordance with the following conditions:

(a) The additive GLA safflower oil is produced in the oil obtained from whole seeds or partially dehulled seeds or both obtained from a Carthamus tinctorius L. safflower Centennial variety genetically engineered to express the delta-6-desaturase gene from Saprolegnia diclina Humphrey. The 453 amino acid, delta-6-desaturase enzyme converts the fatty acid linoleic acid to GLA during seed development. This GLA safflower oil may be safely used in complete dry adult maintenance dog food as a source of GLA and other omega-6 fatty acids in accordance with the following prescribed conditions:

(1) The GLA safflower oil obtained from the seeds of the genetically engineered safflower Centennial variety may be blended with oil obtained from seeds of non-engineered oleic acid safflower varieties in order to meet the specifications required for the additive or the blend in paragraph (a)(2) of this section.

(2) The additive or a safflower oil blend containing the additive for use in animal food meets the following specifications:

(i) Crude fat content of the GLA safflower oil or its blend is not less than 99.5 percent.

(ii) GLA content is between 400 and 450 milligrams (mg) GLA per gram of the GLA safflower oil or its blend.

(iii) Total content of stearidonic acid and cis, cis-6,9-octadecadienoic acid in the GLA safflower oil or its blend must not exceed a total of 0.3 percent.

(3) Addition of GLA safflower oil, or its blend, to complete dry adult maintenance dog food must meet the following:

(i) Addition of the oil or its blend cannot provide more than 36 mg GLA per kilogram body weight of the dog per day in more than 86 mg of the GLA safflower oil or its blend. This maximum addition rate of the GLA safflower oil, or its blend, is 0.3 percent of a complete dry adult maintenance dog food containing 3,600 kilocalories of metabolizable energy per kilogram of food as-fed.

(ii) Adjustments must be made for dog food formulas of different caloric density and/or that are fed to specific weights, breeds, or dogs of different activity levels to meet the requirements of this paragraph.

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

(1) The name, gamma-linolenic acid (GLA) safflower oil.

(2) A guarantee for the minimum content of gamma-linolenic acid.

(3) Adequate directions for use such that the finished animal food complies with the provisions of paragraph (a)(3) of this section.

Dated: August 4, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-17214 Filed: 8/14/2017 8:45 am; Publication Date: 8/15/2017]