4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2010-F-0537]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA 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 seed meal from a variety of bioengineered safflower in cattle and poultry feeds. 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 THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section V of this document for information on the filing of objections.

ADDRESSES: You may submit either electronic or written objections and a request for a hearing, identified by Docket No. FDA-2010-F-0537, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and docket number for this rulemaking. All objections received will be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting objections, see the "Objections" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or 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: Isabel W. Pocurull, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5877, isabel.pocurull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of October 20, 2010 (75 FR 64733), FDA announced that a food additive petition (animal use) (FAP 2267) had been filed by Arcadia

Biosciences, Inc., 202 Cousteau Pl., suite 105, Davis, CA 95618. The petition proposed to amend the food additive regulations to provide for the safe use of seed meal from a variety of bioengineered safflower (Carthamus tinctorius L.) in cattle and poultry feeds. The safflower variety has been bioengineered to contain a gene from the water mold Saprolegnia diclina responsible for production of gamma-linolenic acid in the seed oil. Seed meals are the ground residues obtained after processing seeds to extract their oil and are a common ingredient in livestock feed. The notice of filing provided for a 30-day comment period on the petitioner's environmental assessment.

II. Conclusion

FDA concludes that the data establish the safety and utility of gamma-linolenic acid safflower meal for use as proposed 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.

IV. Environmental Impact

The Agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may

be seen in the Division of Dockets Management (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. 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 21 CFR part 573 continues to read as follows:

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

2. Add § 573.490 to read as follows:

§ 573.490 Gamma-linolenic acid safflower meal.

The food additive consists of the meal obtained after the removal of most of the oil 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 gamma-linolenic acid during seed development. The resulting additive may be safely used in cattle and poultry feeds in accordance with the following prescribed conditions:

(a) The additive shall contain not less than 20 percent crude protein, not more than 40 percent crude fiber, not more than 10 percent moisture, and not more than 2 percent crude fat.

(b) The crude fat in the additive meets the following specifications:

(1) Gamma-linolenic acid content not to exceed 55 percent.

(2) Total content of stearidonic acid and cis, cis-6, 9-octadecadienoic acid not to exceed a total of 0.5 percent.

(3) Total content of palmitic, stearic, oleic, linoleic, and other associated fatty acids to exceed a total of 40 percent.

(c) The additive is used or intended for use in cattle and poultry feeds as a source of protein in accordance with good manufacturing and feeding practices.

(d) To assure safe use of the additive, in addition to the other information required by the Food, Drug, and Cosmetic Act, the label and labeling of the additive, any feed premix, or complete feed shall bear the following:

(1) The name of the additive or the common name, safflower meal.

(2) Adequate directions for use in cattle and poultry feeds.

(e) The additive may be identified by the common or usual name, safflower meal.

Dated: June 16, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015-15220 Filed: 6/19/2015 08:45 am; Publication Date: 6/22/2015]