4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2011-F-0765]

Nexira; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Nexira proposing that the food additive regulations be amended to provide for the expanded safe use of acacia gum (gum arabic) in foods.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register on December 20, 2011 (76 FR 78866), FDA announced that a food additive petition (FAP 1A4784) had been filed by Nexira, c/o Keller and Heckman LLP, 1001 G St., NW., Suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 172.780 Acacia (gum arabic) (21 CFR 172.780) to provide for the expanded safe use of acacia gum (gum arabic) in food.

Under 21 CFR 171.1(c)(H), either a claim of categorical exclusion under 21 CFR 25.30 or § 25.32 (21 CFR 25.32) or an environmental assessment under 21 CFR 25.40 is required to be submitted in a food additive petition. A claim of categorical exclusion under § 25.32(k) was submitted with the petition, which applies to substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food. The Agency reviewed the claim of categorical exclusion submitted by the petitioner and stated in the original filing notice its determination that, under § 25.32(k), the proposed action was of a type that does not individually or cumulatively have a significant effect on the human environment, and therefore, neither an environmental assessment nor an environmental impact statement is required.

However, upon further review of the petition, the Agency has decided that the food additive may act to replace macronutrients in food and, therefore, the categorical exclusion in § 25.32(k) is not applicable for the proposed action. The Agency informed the petitioner of this decision, who subsequently submitted an environmental assessment.

The potential environmental impact of this petition is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy

Act (40 CFR 1501.4(b)), the Agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see DATES and ADDRESSES) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the Agency finds that an environmental impact statement is not required, and this petition results in a regulation, the notice of availability of the Agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.51(b).

Dated: August 28, 2012.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

[FR Doc. 2012-21639 Filed 08/31/2012 at 8:45 am; Publication Date: 09/04/2012]