4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2009-F-0303]

Ajinomoto Co., Inc.; 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 Ajinomoto Co., Inc., to indicate that the petitioned additive, N-[N-[3-(3-hydroxy-4-methoxyphenyl) propyl-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate (proposed additive name Advantame, CAS Reg. No. 714229-20-6), is for use as a non-nutritive sweetener and flavor enhancer in foods generally, except meat and poultry. The previous filing notice indicated that the proposed additive was for use as a non-nutritive sweetener in tabletop applications and powdered beverage mixes.

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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Center for Food Safety and Applied Nutrition (HFS-265),

Food and Drug Administration,

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240-402-1264.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 21, 2009 (74 FR 35871), FDA announced that a food additive petition (FAP 9A4778) had been filed by Ajinomoto, Co., Inc., c/o Ajinomoto Corporate Services LLC, 1120 Connecticut Ave. NW., suite 1010, Washington, DC 20036 (now c/o Ajinomoto North America, Inc., 400 Kelby St., Fort Lee, NJ 07024). In the notice of filing, FDA announced that the petitioner proposed that the food additive regulations in part 172 Food Additives Permitted For Direct Addition to Food for Human Consumption (21 CFR part 172) be amended to provide for the safe use of N-[N-[3-(3-hydroxy-4-methoxyphenyl) propyl-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate (CAS Reg. No. 714229–20–6) as a non-nutritive sweetener in tabletop applications and powdered beverage mixes. The petition was filed under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348).

Subsequent to publication of the filing notice, Ajinomoto Co., Inc., amended its petition to provide for the safe use of N-[N-[3-(3-hydroxy-4-methoxyphenyl) propyl-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate as a non-nutritive sweetener and flavor enhancer in foods generally, except meat and poultry. Therefore, FDA is amending the filing notice of July 21, 2009, to indicate that the petitioner has proposed that the food additive regulations in part

172 be amended to provide for the use of N-[N-[3-(3-hydroxy-4-methoxyphenyl) propyl-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate (proposed additive name Advantame, CAS Reg. No. 714229-20-6), as a non-nutritive sweetener and flavor enhancer in foods generally, except meat and poultry.

The potential environmental impact of this petition is being reviewed. To encourage public participation consistent with regulation 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 either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. 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, and will be posted to the docket at http://www.regulations.gov. 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: October 22, 2012.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

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