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Certifier	JAN WILSON

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F-0187]

Monsanto Co.: Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Monsanto Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of L-Phenylalanine, N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester as a general use sweetener. Monsanto proposes that this additive be identified as neotame.

DATES: Written comments on the petitioner's environmental assessment by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Blondell Anderson,

Center for Food Safety and Applied Nutrition (HFS-206),

Food and Drug Administration,

200 c St. SW.>

Washington, DC 20204,

202-418-3106.

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SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9A4643) has been filed by Monsanto Co., 5200 Old Orchard Rd., Skokie, IL 60077. The petition proposes to amend the food additive regulations in part 172 Food Additives Permitted for Direct Addition to Food for Human Consumption to provide for the safe use of N-[N-(3,3-dimethylbutyl)-L- α -aspartyl]-L-phenylalanine 1-methyl ester as a general use sweetener. Monsanto proposes the sweetener be identified as **neotame**.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated 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 display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above 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

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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 25.40(c).

Dated: January 28, 1999
January 28, 1999

Laura M. Tarantino

Laura M. Tarantino
Acting Director
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jen Windhorst