Dated: February 1, 1999.

Patricia Montoya,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 99–3006 Filed 2–5–99; 8:45 am]

BILLING CODE 4184–01–P

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]-,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 April 10, 1999.

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.

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 April 10, 1999, 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 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.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–2851 Filed 2–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting is open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 26, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss experience since approval for marketing, benefits, and risks of Rezulin™ (troglitazone, Parke-Davis Pharmaceutical Research, a Division of Warner-Lambert) in the treatment of type 2 diabetes mellitus.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 23, 1999. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 23, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. In addition, an open public session will be conducted after the scientific presentations.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 26, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–2852 Filed 2–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1165]

Draft Guidance for the Content of Premarket Notifications (510(k)'s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance for the Content of

Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.'' This guidance is neither final nor is it in effect at this time. This draft guidance describes the types of information that should be submitted in a premarket notification to support a decision of substantial equivalence for an extracorporeal shock wave lithotripter indicated for the fragmentation of kidney and ureteral calculi, including potential special controls. Although renal and ureteral extracorporeal shock wave lithotripters are currently classified into class III (premarket approval), elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify these devices to class II (special controls). It is anticipated that this draft guidance will become effective if/when a final rule regarding this reclassification has been issued.

DATES: Written comments concerning this draft guidance must be received by May 10, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5'' diskette of the draft guidance document entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Written comments concerning this draft guidance must be submitted to the Dockets Management Branch, (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John H. Baxley, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Background

Extracorporeal shock wave lithotripters for the fragmentation of kidney and ureteral calculi are currently postamendments class III devices, requiring either an approved premarket approval (PMA) application or declared complete product development protocol (PDP) prior to commercial distribution in the United States. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify extracorporeal shock wave lithotripters from class III into class II (special controls). To facilitate the proposed reclassification, FDA has prepared the draft guidance entitled ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi.'' This draft guidance describes the special controls that FDA is including in the proposed rule, and it also provides general guidance to industry on the content of premarket notifications for these devices.

A meeting of the Gastroenterology and Urology Devices Advisory Panel of the Medical Devices Advisory Committee was held on July 30, 1998, to seek its recommendations on this proposed reclassification, including advice on special controls and the content of premarket notifications. The panel unanimously voted to reclassify the extracorporeal shock wave lithotripter for the fragmentation of renal and ureteral stones into class II. Comments from the panel have been incorporated into this draft guidance document.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the reclassification of extracorporeal shock wave lithotripters indicated for the fragmentation of kidney and ureteral calculi. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1226) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information.

IV. Comments

Interested persons may, on or before May 10, 1999, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. 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. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 21, 1999.

Linda S. Kahn,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–2690 Filed 2–5–99; 8:45 am]

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