

**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 5A4460) has been filed by Ecolab Inc., 370 North Wabasha St., St. Paul, MN 55102. The petition proposes to amend the food additive regulation in § 173.315 *Chemicals used in washing or to assist in the lye peeling of fruits and vegetables* (21 CFR 173.315) to provide for the safe use of a mixture of peroxyacetic acid, acetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1,1-diphosphonic acid to control microbial growth in water contacting fruits and vegetables.

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 public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may on or before August 14, 1995, 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: July 3, 1995.

**Alan M. Rulis,**

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

[FR Doc. 95-17235 Filed 7-12-95; 8:45 am]

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[Docket No. 95G-0156]

**Sandoz Nutrition Corp.; Filing of Petition for Affirmation of GRAS Status**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Sandoz Nutrition Corp. has filed a petition (GRASP 5G0414), proposing to affirm that partially hydrolyzed guar gum (PHGG) is generally recognized as safe (GRAS) as an ingredient in human food.

**DATES:** Written comments by September 26, 1995.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFS-207), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3107.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409(b)(5) (21 U.S.C. 321(s) and 348(b)(5))) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that Sandoz Nutrition Corp., 5320 West Twenty Third St., P.O. Box 370, Minneapolis, MN 55440, has filed a petition (GRASP 5G0414), proposing that PHGG be affirmed as GRAS for use in human food. The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in § 170.30 (21 CFR 170.30) and § 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of the suitability for GRAS affirmation.

The potential environmental impact of this action is being reviewed. If 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).

Interested persons may, on or before September 26, 1995, review the petition and/or file comments (two copies of any comments should be filed and should be identified with the docket number

found in brackets in the heading of this document) with the Dockets Management Branch (address above). Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 23, 1995.

**Alan M. Rulis,**

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

[FR Doc. 95-17233 Filed 7-12-95; 8:45 am]

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[Docket No. 95N-0202]

**Drug Export; Preservative-Free Intravenous Sodium Edecrin® (Ethacrynate Sodium) 50 Milligrams (mg) Ethacrynic Acid Equivalent/50 Milliliters (mL) in 60 mL Glass Bottle**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Merck & Co. has filed an application requesting approval for the export of the human drug Preservative-Free Intravenous Sodium Edecrin® (ethacrynate sodium) 50 mg ethacrynic acid equivalent/50 mL in 60 mL glass bottle to Germany through the Netherlands for further packaging and labeling.

**ADDRESSES:** Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

**FOR FURTHER INFORMATION CONTACT:** James E. Hamilton, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-3150.

**SUPPLEMENTARY INFORMATION:** The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Merck & Co., West Point, PA 19486, has filed an application requesting approval for the export of the human drug Preservative-Free Intravenous Sodium Edecrin® (ethacrynate sodium) 50 mg ethacrynic acid equivalent/50 mL in 60 mL glass bottle to Germany through the Netherlands for packaging and labeling. This product is used in the treatment of accumulation of fluid in tissues (edema, ascites) due to heart, hepatic, or renal disease as well as edemas of the following origin: Edema or ascites caused by tumor compression, lymphedema, and idiopathic edema. The product is being manufactured by a revised process. The firm has new drug application approval for a product containing a thimerosal preservative. The application was received and filed in the Center for Drug Evaluation and Research on May 17, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by July 24, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner

of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: June 26, 1995.

**Betty L. Jones,**

*Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.*

[FR Doc. 95-17236 Filed 7-12-95; 8:45 am]

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## National Institutes of Health

### Warren Grant Magnuson Clinical Center: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of High Resolution PET Scanner Using Scintillation Cameras

**AGENCY:** National Institutes of Health, PHS, DHHS.

**ACTION:** Notice.

**SUMMARY:** The Nuclear Medicine Department in the Clinical Center at the Warren Grant Magnuson Clinical Center is seeking a collaborator with expertise in imaging equipment. The primary focus of this collaboration will be the development and commercialization of an imaging device that is capable of three distinct types of imaging at high resolution: Single photon planar imaging, single photon emission computed tomography (SPECT), and positron emission tomography (PET). An invention that has set the groundwork for this technology is claimed in U.S. Patent Applications 08/235,310, entitled "Variable Axial Aperture Positron Emission Tomography Scanner" (filed April 29, 1994) and (CIP) 08/357,574 (filed December 15, 1994). These patents have been filed for the initial phase of foreign filing (PCT) designating all states. NCI seeks a collaborator that will apply the technology to develop imagers for human subjects and/or for high resolution PET imaging of small animals.

Sponsors will be selected based on their ability to develop and commercialize the new imaging technology. NCI will enter into CRADA negotiations with the chosen sponsor with the intention of awarding a CRADA.

The term of the CRADA(s) is anticipated to be three (3) to five (5) years.

**ADDRESSES:** Inquiries and proposals regarding this opportunity should be addressed to either Michelle Rhyu or Bill Cotreau (Tel # 301-496-0477, Fax# 301-402-2117), Office of Technology Development, National Cancer Institute,

Building 31, Room 4A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

**DATES:** Interested parties should notify this office in writing by September 11, 1995. Respondents will then be given an additional sixty (60) days for filing a formal proposal.

**SUPPLEMENTARY INFORMATION:** A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987. Under the present proposal, the CRADA will focus on developing the following technology:

An instrument has been devised that utilizes conventional scintillation cameras to support single photon planar imaging, single photon emission computed tomography (SPECT), and positron emission tomography (PET). These multiple capabilities rely on the device's ability to efficiently detect gamma rays at single photon energies (<200 keV) and higher positron annihilation energies (511 keV) required for PET. This dual ability is conferred by pivoting the detectors in conventional scintillation devices, which are capable of only SPECT and planar imaging, thereby increasing the path length of the high energy positron in the detector and enabling its detection. The cameras may rotate about a fixed target, or stationary cameras may surround a rotating target. The invention makes PET scanning on small animals feasible, allowing the economical collection of test data. Moreover, the invention presents a promising approach to economically increasing the detection capability of conventional SPECT scanners for humans.

Two broad advantages are provided by the present invention: (1) Resolution of PET is improved from 6mm to 2-3mm, making possible the resolution of organs in small animals. This expands the usefulness of small animals in research, for example in determining how test tracer molecules are incorporated into tumors, or how specific therapies affect tumor growth. The invention affords the advantage of using small animals, which are easier and less costly to maintain than larger animals. The ability to carry out PET analysis on smaller animals also circumvents the need to dissect the animal in order to assay an effect, greatly reducing the number of animals required for a study. (2) Applying this technology to human imagers, the invention provides a cost-effective way of improving diagnostic capabilities for