Eligible Applicants

Eligible applicants include non-profit and for-profit organizations. Thus, universities, colleges, research institutions, hospitals, public and private organizations, State and local health departments and small, minority and/or woman-owned businesses are eligible for these grants.

Availability of Funds

Approximately $225,000 will be available in Fiscal Year 1989 to fund approximately 15 awards. The awards will range from $5,000 to $50,000 with the average award being approximately $15,000. The awards will be funded with a 12-month budget and project period. The funding estimate outlined above may vary and is subject to change.

The following are examples of the most frequently encountered costs which may or may not be charged to the grant:

1. Grant funds may be used for direct cost expenditures: salaries, speaker fees, rental of necessary equipment, registration fees, transportation costs (not to exceed economy class fare), and travel of non-Federal employees.

2. Funds may *not* be used for the purchase of equipment, payments of honoraria, indirect costs, organizational dues, entertainment/personal expenses, cost of travel and payment of a full-time Federal employee or for per diem or expenses other than local mileage for local participants.

Purpose

The purpose of the HIV-related conference support grants are to provide partial support for non-Federal conferences to intensify efforts to prevent the transmission of HIV infection.

Program Requirements

The programmatic areas of interest in which applications are being solicited by CDC for HIV-related conferences are: (1) Disease prevention; (2) information/education (specificaly regarding the cause and transmission of the virus); and (3) biostatistics.

Evaluation Criteria

The review of applications will be conducted in accordance with PHS Grants Administration Manual, Part 134, Objective Review of Grant Applications. Applications for support of the types of conferences listed in the Program Requirements section above will be evaluated and ranked for funding.

The major factors to be considered in the evaluation of responsive applications will include:

1. *Proposed Program* (50%).
2. *Program Personnel* (30%).
3. *Applicant Capability* (20%).
4. *Program Budget*—(Not Scored) Comments Only.

Other requirements

Recipients must comply with the document titled: Content of Aids-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Education Sessions (October 1988) [54 FR 10049, March 9, 1989]. In complying with the Program Review Panel requirements contained in the document, recipients are encouraged to use an existing Program Review Panel such as the one created by the health department's AIDS/HIV Prevention Program.

E.O. 12372 Review

Applications are not subject to review as governed by Execuvtive Order 12372, entitled Intergovernmental Review of Federal Programs.

CFDA Number

The Catalog of Federal Domestic Assistance number is 13.118.

Application Submission and Deadline

The original and two copies of the application shall be submitted on Form PHS 5161–1 in accordance with the following schedule. The schedule also sets forth *anticipated* award date:

Deadline Date

Application: June 15
Award Date: September 1

Applications must be submitted on or before the deadline date to: Mr. Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE Room 415, Mailstop E 14, Atlanta, Georgia 30305.

Deadline:

Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date, or

2. Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications:

Applications which do not meet the *Deadline* criteria, outlined in the paragraph immediately above, are considered late applications, will not be considered in the current competition, and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description, information on application procedures and an application package may be obtained from Ms. Donna M. Rushin, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disase Control, 255 East Paces Ferry Road, NE Room 415, Mailstop E 14, Atlanta, Georgia 30305, (404) 842–6545 or FTS 236–6545.

Please refer to Announcement Number 924 when requesting information and submitting any application on the Request For Assistance.

Dated: May 3, 1989.

Robert L. Foster,

Acting Director, Office of Program Support, Centers for Disease Contron.

[FR Doc. 89–11162 Filed 5–9–89; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

Request for Nominations for Voting Members; Science Advisory Board

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Science Advisory Board to the National Center for Toxicological Research. Three vacancies will occur on the committee on June 30, 1989.

DATE: Nominations should be submitted by June 15, 1989.

ADDRESS: All nominations for membership should be submitted to Ronald F. Coene (address below).

FOR FURTHER INFORMATION CONTACT: Ronald F. Coene, National Center for Toxicological Research (HFT–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3155.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations of members to serve on the Science Advisory Board. The function of the board is to advise the Director, National Center for Toxicological Research, in establishing and implementing a research program that will assist the Commissioner of Food and Drugs in fulfilling his responsibilities. The board provides the extra-agency review to ensure that research programs and methodology

development at the National Center for Toxicological Research are scientifically sound and pertinent to environmental problems.

Criteria for Members

Persons nominated for membership on the Science Advisory Board shall have adequately diversified experience appropriate to the work of the board in such fields as biomedical research and toxicology. The specialized training and experience necessary to qualify the nominee as an expert suitable for appointment is subject to review, but may include experience in medical practice, teaching, and/or research relevant to the field of activity of the committee. The term of office is normally 4 years.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the advisory committee. Nominations shall state that the nominee is willing to serve as a member of the advisory committee and appears to have no conflict of interest that would preclude committee membership. FDA asks potential candidates to provide detailed information concerning such matters as employment, financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

FDA has a special interest in assuring that women, minority groups, and the physically handicapped are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, and handicapped candidates.

This notice is issued under the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)) and 21 CFR Part 14, relating to advisory committees.

Dated: May 3, 1989.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-11172 Filed 5-9-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89F-0115]

Huls America, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Huls America, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the additional use of Nylon 12 in coatings for repeated use in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Maco, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 9B4137) has been filed by Huls America, Inc., 80 Centennial Avenue, Piscataway, NJ 08855-0456 proposing that § 177.1500 *Nylon resins* (21 CFR 177.1500) be amended to permit the additional use of Nylon 12 in coatings intended for repeated use in contact with food.

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).

Dated: April 28, 1989.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-11173 Filed 5-9-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89G-0126]

Gist-Brocades Inc.; Filing of Petition for Affirmation of Gras Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Gist-brocades Inc., has filed a petition (GRASP 9G0349) proposing that chymosin derived from the fermentation of a genetically modified *Kluyveromyces marxianus* var. *lactis* (*K. lactis*) be affirmed as generally recognized as safe (GRAS) as a direct human food ingredient.

DATE: Comments by July 10, 1989.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Eric L. Flamm, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that a petition (GRASP 9G0349) has been filed by Gist-brocades Inc., P.O. Box 241068, Charlotte, NC 28224, proposing that chymosin derived by fermentation from *K. lactis* genetically modified to contain and express a prochymosin gene be affirmed as GRAS for use as a direct human food ingredient.

The GRAS affirmation petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 and 170.35 (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 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 July 10, 1989 review the petition and/or file comments (two copies, 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. A copy of the petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 1, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-11174 Filed 5-9-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89E-0128]

Determination of Regulatory Review Period for Purposes of Patent Extension; Cefpiramide Sodium for Injection

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Cefpiramide Sodium for injection and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce (PTO), for the extension of a patent which claims that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDS's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product Cefpiramide Sodium for injection. Cefpiramide Sodium for injection is indicated for the treatment of serious infections caused by susceptible strains of the designated microorganisms in the following diseases: (1) Pneumonia caused by *streptococcus pneumoniae haemophilus influenza* (*beta*-lactamase negative), and *staphylococcus aureus* (including penicillinase-producing and methecillin-susceptible strains); and (2) skin and skin structure infections caused by *staphylococcus aureus* (including penicillinase-producing and methicillin-susceptible strains), *streptococcus pyogenes*, and *streptococcus agelactiae*.

Subsequent to this approval, PTO received a patent term restoration application for Cefpiramide Sodium for injection (U.S. Patent No. 4,156,724) from Sumitomo Chemical Co. Ltd., and requested FDA's assistance in determining the eligibility of this patent for patent term restoration. In a letter dated April 18, 1989, FDA advised PTO that the human drug product had undergone a regulatory review period. The letter also stated that the active ingredient, Cefpiramide Sodium, represented the first permitted commercial marketing or use. Shortly thereafter, PTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Cefpiramide Sodium for injection is 2,015 days. Of this time, 1,464 days occurred during the testing phase of the regulatory review period, while 551 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* July 29, 1983. FDA has verified the applicant's claim that July 29, 1983, is the date that the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act:* July 31, 1987. FDA has verified the applicant's claim that the date the new drug application (NDA 50-633) was initially submitted to FDA was on July 31, 1987.

3. *The date the application was approved:* January 31, 1989. FDA has verified the applicant's claim that NDA 50-633 was approved on January 31, 1989.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension In its application for patent extension, the applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 10, 1989 submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 6, 1989, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 1030.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 3, 1989

Stuart L. Nightingale

Associate Commissioner for Health Affairs

[FR Doc. 89-11175 Filed 5-9-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89E-0096]

Determination of Regulatory Review Period for Purposes of Patent Extension; Mesnex™; Correction

AGENCY: Food and Drug Administration.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the notice of its determination of the regulatory review period for purposes of patent extension for Mesnex™ (mesna) that appeared in the **Federal Register** of April 12, 1989 (54 FR 14685). The notice stated that the patent applicant requested 730 days of patent extension. It should have stated that 819 days of patent extension were requested. This document corrects that error.