Dated: June 8, 1992.

Emily C. Karam,

Director, Information Management Division.

[FR Doc. 92-14317 Filed 6-17-92; 8:45 am]

BILLING CODE 6820-23-M

Information Collection Activities Under Office of Management and Budget Review

AGENCY: Office of the Comptroller (BCDP), GSA.

SUMMARY: The GSA hereby gives notice under the Paperwork Reduction Act of 1980 that it is requesting the Office of Management and Budget (OMB) to renew expiring information collection, 3090-0007, Contractor's Qualification and Financial Information. This information is used to determine whether prospective contractors are financially responsible.

ADDRESSES: Send comments to Ed Springer, GSA Desk Officer, room 3235, NEOB, Washington, DC 20503, and to Mary L. Cunningham, GSA Clearance Officer, General Services Administration (CAIR), 18th & F Street NW, Washington, DC 20405.

Annual Reporting Burden

Respondents 6,250; annual responses: 1.2; average hours per response: 1.8667; burden hours: 14,000.

FOR FURTHER INFORMATION CONTACT: Edgar K. Davis, (202) 501-0208. Copy of Proposal: May be obtained from the Information Collection Management Branch (CAIR), 7102, GSA Building, 18th & F St. NW, Washington, DC 20405, by telephoning (202) 501-2691, or by faxing your request to (202) 501-2727.

Dated: June 9, 1992.

Emily C. Karam,

Director, Information Management Division.

[FR Doc. 92-14318 Filed 6-17-92; 8:45 am]

BILLING CODE 6820-23-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Drug Abuse Human Development Research Review Committee; Establishment

Pursuant to section 510(j) of the Public Health Service Act, 42 U.S.C. 290aa(j), and the Federal Advisory Committee Act, 5 U.S.C. appendix 2, the Acting Administrator, Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), announces the establishment, effective June 4, 1992, of the following National Institute on Drug Abuse initial review committee:

Drug Abuse Human Development Research Review Committee

The duration of this committee is continuing unless formally determined by the Administrator, ADAMHA, that termination would be in the best public interest.

Dated: June 12, 1992.

Elaine M. Johnson,

Acting Administrator, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 92-14310 Filed 6-17-92; 8:45 am]

BILLING CODE 4160-20-M

Centers for Disease Control

[Program Announcement Number 275]

National Institute for Occupational Safety and Health; Demonstration of an Ergonomic Intervention in the Red-Meat Packing Industry; Notice of Availability of Funds for Fiscal Year 1992

Introduction

The Centers for Disease Control (CDC), the Nation's prevention agency, announces the availability of Fiscal Year 1992 funds for a cooperative agreement to develop an intervention to reduce ergonomic hazards in red-meat packing plants.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Occupational Safety and Health. (For ordering a copy of Healthy People 2000 see the section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

Authority

This program is authorized under section 21(a) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 670(a)).

Eligible Applicants

Eligible applicants include non-profit and for-profit organizations. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, state and local health departments or their bona fide agents or instrumentalities, and small, minority and/or women-owned businesses are eligible for these cooperative agreements.

Availability of Funds

Approximately $150,000 is available in Fiscal Year 1992 to fund one or more awards. If multiple awards are made, it is expected the awards will range from $30,000 to $70,000. If a single award is made, it is expected the award will be approximately $150,000. The awards are expected to begin on or about September 30, 1992, for a 12-month budget period within a project period of 1 year.

Purpose

The purpose of this cooperative agreement is to assist in the development of an ergonomic team comprised of plant personnel at a red-meat packing plant. The team, with recipient assistance, will identify ergonomic problems in a task or series of tasks, and develop work practice, engineering, and/or administrative controls to solve the problems. Lessons learned from this targeted project will be used to sustain continued ergonomic improvements in the plant and to transfer information about the team approach to other plants within the industry.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for conducting activities under A., below, and CDC will be responsible for conducting activities under B., below.

A. Recipient Activities

1. The recipient should secure and sustain a formal relationship with a red-meat (pork and/or beef) packing plant (trial plant) and its work force that assures commitment of the participants to the project and assures access to the plant by the recipient for the project period. The trial plant agrees to make information learned available publicly.

2. With collaboration, the recipient will plan and implement a demonstration ergonomic project at a red-meat packing plant which should include the following elements:

a. *Targeting, with CDC and that plant collaboration, a task or series of tasks within the trial plant for the intervention.*

The task(s) selected will be from among those that are associated with a known high risk of cumulative trauma disorders (CTDs). These include various kill and fabrication tasks. (Example: Fabrication tasks are clod pulling, chuck boning, dropping founds, and boning hams.)

b. *Developing a participatory ergonomic team.*

The team should be comprised of workers and supervisors from the selected job area and other plant personnel such as engineering, management, and medical staff as appropriate.

c. *Training the team in ergonomic awareness.*

The recipient should introduce ergonomic concepts that enable the team to recognize CTD risk factors, ergonomic hazards, analyze tasks, and refine and implement ergonomic controls.

d. *Developing controls.*

The recipient, in collaboration with CDC, will assist the ergonomic team's development of engineering, work practice, and/or administrative controls to reduce ergonomic hazards associated with the selected task.

e. *Implementing controls.*

The recipient should assist the team's implementation of the controls.

(Note: Cooperative agreement funds are not available to be spent by the meat packing plant for the controls.)

f. *Evaluation.*

Using concepts introduced during team training, the recipient will facilitate a team process of evaluation and feedback to refine and improve implemented controls. Measures of the effectiveness of controls could include a demonstrable reduction of ergonomic risk factors.

3. The recipient will monitor and evaluate the success of the team approach. Measures of team success may include effectiveness of implemented controls, whether the team activity is continued and whether controls are sustained and improved.

4. In collaboration with CDC, the recipient will develop a written case study of the participatory ergonomic projects.

B. CDC Activities

1. Provide technical information and support concerning ergonomics.

2. Provide technical assistance to the recipient in: (a) Choosing the task or series of tasks for the intervention; (b) developing team awareness training; (c) developing control measures for project success; and (d) developing a case study report.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria:

A. Demonstrate Technical Ability (15%)

Understands ergonomic problems of meat packing plants and understands participatory ergonomic interventions.

B. Program personnel (15%)

Ability to provide the staff, knowledge and other resources and experience to carry out the project. The staff is competent and experienced in the skills required in the scope of work. Resumes of staff should reflect not only academic qualifications but also length and variety of experience in similar tasks.

C. Proposed Plan (30%)

Proposed trial plant is committed to a team approach to ergonomic improvements and is representative of the red-meat packing industry in terms of employment and product and process. (Letters from the proposed trial plant and its labor representative, if applicable, documenting their commitment to the project should be included for the proposal to be considered for an award.)

D. Approach and Capability (30%)

Approach is sound. Proposal describes an approach and goals consistent with the activities or suggests alternative approaches to achieve the same purpose. Application outlines reasonable approaches to task targeting team building, team training, and control development, implementation, and refinement. Proposed project monitoring and evaluation methods and measures are reasonable.

E. Schedule (10%)

Proposed schedule is reasonable and consistent with the proposed approach.

F. Budget (Not Scored)

The budget will be evaluated to the extent it is reasonable, clearly justified, and consistent with the intended use of funds.

Executive Order 12372 Review

Applications are not subject to review by Executive Order 12372, Intergovernmental Review of Federal Programs.

Catalog of Federal Domestic Assistance Number (CFDA)

The Catalog of Federal Domestic Assistance Number for this program is 93.283.

Application and Submission Deadline

The original and two copies of the application PHS Form 5161–1 must be submitted to 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 300, Mailstop E–14, Atlanta, Georgia 30305, on or before August 15, 1992.

1. Deadline.

Applications will be considered to have met the deadline if they are either:

a. Received on or before the deadline date, or

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must 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.)

2. *Late Applicants:* Applications which do not meet the criteria in 1.a. or 1.b. above are considered late applications. Late applications will be returned to the applicant.

Where to Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and telephone number and will need to refer to Announcement Number 275. You will receive a complete program description, information on application procedures, and application forms.

If you have any questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Oppie Byrd, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., room 300, Mailstop E–14, Atlanta, GA 30305, (404) 842–6630. Programmatic technical assistance is available from Christopher Gjessing, Division of Physical Sciences and Engineering, National Institute for Occupational Safety and Health, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, (513) 841–4354.

Please refer to Announcement Number 275 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1), referenced in the INTRODUCTION, through the Superintendent of Documents, Government Printing Office, Washington, DC, 20402–9325, (202) 783–3238.

Copies of OSHA's ERGONOMICS PROGRAM MANAGEMENT GUIDELINES FOR MEATPACKING PLANTS (OSHA Publication No. 3123) may be ordered through OSHA Publications, U.S. Department of Labor, 200 Constitution Ave. NW., North 3101, Washington DC, 20210.

Dated: June 11, 1992.

J. Donald Millar,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control.

[FR Doc. 92-14331 Filed 6-17-92; 8:45 am]

BILLING CODE 4160-19-M

Food and Drug Administration

[Docket No. 92D-0019]

Center for Veterinary Medicine Policy and Procedures Guide: NADA Review of Dosage Form Oral Electrolytes; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of its new Center for Veterinary Medicine (CVM) Policy and Procedures Staff Manual Guide 1240.3150 entitled "NADA Review of Dosage Form Oral Electrolytes." The guide discusses ways of satisfying statutory and other requirements concerning effectiveness, target animal and human food safety, environmental impact, chemistry/manufacturing, and labeling.

DATES: Written comments by August 17, 1992.

ADDRESSES: Submit written requests for single copies of the Policy and Procedures Guide 1240.3150 entitled "NADA Review of Dosage Form Oral Electrolytes" to the Communications and Education Branch (HFV-12), Center For Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on Guide 1240.3150 to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding general information on guide 1240.3150: Steven M. Solomon, Center for Veterinary Medicine (HFV-214), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8758.

Regarding information on submitting new animal drug applications for approval: George K. Haibel, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8649.

SUPPLEMENTARY INFORMATION: Dosage form oral electrolyte products for animal use are intended for the mitigation of fluid and electrolyte losses and subsequent disruptions of metabolic activity associated with animal disease. Dosage form oral electrolyte products for use in animals are ordinarily new animal drugs as defined in section 201(w) of the Federal Food, Drug, and Cosmetic Act (the act). Each such product that is a new animal drug requires an approved new animal drug application (NADA) as provided in section 512 of the act prior to manufacture and marketing. Guide 1240.3150 provides internal guidance to NADA reviewers on how the statutory requirement of a substantial evidence of effectiveness can be satisfied for a dosage form oral electrolyte product. It also provides internal guidance on the review of NADA's for conformance to statutory and other requirements for target animal safety, human food safety, environmental impact, chemistry/manufacturing, and labeling. This guide does not bind the agency nor does it create or confer any rights, privileges, or other benefits for or on any person.

Interested persons may submit written comments on the guide to the Dockets Management Branch (address above). Comments will be considered in evaluating the need to amend the guide. Two copies of comments should be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The guide and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Requests for assistance in filing applications for oral electrolyte products should be directed to the Office of New Animal Drug Evaluation (HFV-100), Center For Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8620 or 301-295-8623.

Dated: May 27, 1992.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 92-14353 Filed 6-17-92; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 92C-0179]

Microbio Resources, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Microbio Resources, Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of comminuted *Haematococcus pluvialis* algae meal as a color additive in aquaculture feeds.

FOR FURTHER INFORMATION CONTACT: Emily Florio, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9515.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 706(d)(1) (21 U.S.C. 376(d)(1))), notice is given that a petition (CAP 1C0237) has been filed by Microbio Resources, Inc., 6150 Lusk Blvd., Suite B-105, San Diego, CA 92121. The petition proposes to amend 21 CFR part 73 of the color additive regulations to provide for the safe use of comminuted *Haematococcus pluvialis* algae meal as a color additive in aquaculture feeds.

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: June 5, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-14382 Filed 6-17-92; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 90G-0412]

Fuji Oil Co., Ltd.; Filling 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 Fuji Oil Co., Ltd., has filed a petition (GRASP 7G0330), proposing to affirm that lipase-protease enzyme preparation derived from *Rhizopus niveus* is

generally recognized as safe (GRAS) as a direct human food ingredient.

DATES: Written comments by August 17, 1992.

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: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–5487.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409(b)(5) (21 U.S.C. 321(s), 348(b)(5))) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that Fuji Oil Co., Ltd., Osaka, Japan, has filed a petition (GRASP 7G0330), proposing that lipase-protease enzyme preparation derived from *Rhizopus niveus* be affirmed as GRAS for use as a direct human food ingredient.

The 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 August 17, 1992, 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: June 5, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92–14383 Filed 6–17–92; 8:45 am]

BILLING CODE 4160–01–F

Investigational New Drugs; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is asking interested drug companies to submit the name and number of any investigational new drug trial placed on clinical hold during fiscal years 1991 and 1992 which the drug companies want reviewed by the committee that periodically reviews selected clinical holds of the Center for Drug Evaluation and Research (CDER). FDA imposes clinical holds on drug studies when it believes it necessary to protect the welfare of clinical subjects. Submissions should be made to the Chief Mediator and Ombudsman to ensure the confidentiality of the request.

DATES: The meeting will be held in August 1992. Drug companies may submit review requests for the August meeting before July 15, 1992.

ADDRESSES: Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, rm. 14–84, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1306.

FOR FURTHER INFORMATION CONTACT: Deborah Wolf, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8046.

SUPPLEMENTARY INFORMATION: FDA is announcing the fourth in a series of meetings of the committee that reviews the clinical holds that CDER has placed on certain investigational new drug trials. If FDA determines that a proposed or ongoing study may pose significant risks for human subjects, or, for Phase 2 or 3 studies, is otherwise seriously deficient, it may impose a clinical hold on a study. FDA is asking interested drug companies to submit to the committee for its review the name and number of any investigational new drug trial placed on clinical hold during fiscal years 1991 and 1992 that the drug companies want the committee to review.

The clinical hold is FDA's primary mechanism for protecting subjects who are involved in investigational new drug trials. A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be placed on one or more of the investigations covered by an investigational new drug application (IND). When a proposed study is placed on clinical hold, subjects may not be given the investigational drug as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug, and patients already in the study should stop receiving therapy involving the investigational drug unless FDA specifically permits it.

In the **Federal Register** of October 2, 1991 (56 FR 49894), the agency published a notice announcing the establishment of an experimental procedure for reviewing clinical holds. The notice described the IND regulations and the provisions governing clinical holds. The notice also described some concerns which IND sponsors have expressed concerning the reasons for imposition of clinical holds.

The procedure involved the creation of a committee composed of senior agency officials to review the process by which clinical holds are imposed. Under the procedure, the committee reviews a number of clinical holds at each of its regularly scheduled meetings. The Chief Mediator and Ombudsman develops the list of clinical holds to be reviewed. Some are selected randomly from CDER's management information system, but others are submitted by IND sponsors. The committee process neither replaces, nor prevents firms from using, the dispute resolution procedures described in the IND regulations (see 21 CFR 312.48).

The committee held a pilot meeting in August 1991 and regular meetings in November 1991 and April 1992, and will hold a meeting in June 1992. The August 1992 meeting will be the fourth regular meeting of the committee.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding privileged commercial information, are available from the Chief Mediator and Ombudsman. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.