Consumption (21 CFR part 172) to provide for the safe use of *Haematococcus* algae astaxanthin as a nutrient supplement.

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 29, 2002.

Leslye M. Fraser,

Acting Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 02–8746 Filed 4–10–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety Research: Availability of Cooperative Agreements; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), in its request for applications (RFA), is announcing the availability of approximately $500,000 in research funds for fiscal year (FY) 2002. These funds will be used to support collaborative research efforts between the Center for Food Safety and Applied Nutrition (CFSAN) and scientists and to complement and accelerate ongoing research in the area of transmissible spongiform encephalopathies (TSE) in order to avoid their presence in the nation's food supply, food additives, and dietary supplements.

DATES: Submit applications by June 10, 2002.

ADDRESSES: Submit completed applications to: Maura Stephanos, Grants Management Specialist, Grants Management Staff (HFA–520), Division of Contracts and Procurement Management, Food and Drug Administration, 5630 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7183, FAX 301–827–7101, e-mail: mstepha1@oc.fda.gov.

Application forms are available either from Maura Stephanos (see previous paragraph) or on the Internet at http://www.grants.nih.gov/grants/funding/phs398/phs398.html.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Maura Stephanos (see **ADDRESSES**).

Regarding the programmatic aspects of this notice: John W. Newland, Microbial Research Coordinator, Office of Science (HFS–06), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1915, e-mail: john.newland@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to reducing the incidence of foodborne illness to the greatest extent feasible and to protecting the integrity of the nation's food supply. Research in food safety seeks to prevent foodborne illness by improving our ability to detect and quantitate foodborne pathogens, toxins and chemicals that could jeopardize the safety of the food supply, and to find new and improved ways to control these agents. CFSAN supports multiyear cooperative agreements intended to help achieve these research goals of reducing the incidence of foodborne illness and ensuring the integrity of foods, food additives, and dietary supplements. This extramural program supports novel collaborative research efforts between CFSAN and scientists, and leverages expertise not found within CFSAN to complement and accelerate ongoing research. Collaborations such as these provide information critical to food safety guidance and policymaking, and stimulate fruitful interactions between FDA scientists and those within the greater research community.

In continuation of this effort, FDA is announcing the availability of research funds for FY 2002 to support research in the following category: The development of proteinase-resistant proteins that can be used as surrogates of infectious prions associated with the family of diseases known as TSE. Approximately $500,000 will be available in FY 2002. FDA anticipates making awards of $100,000 to $250,000 (direct plus indirect costs) per award per year. Support of these agreements may be up to 4 years in duration with the total budget amount not to exceed $250,000 (direct plus indirect costs) per year or a total of $1 million for a 4-year award. Any application received that exceeds the amounts stated previously will not be considered responsive and will be returned to the applicant without being reviewed. The number of agreements funded will depend on the availability of Federal funds to support the projects and on the quality of the applications received. After the first year, additional years of noncompetitive support are predicated upon performance and the availability of Federal funds.

FDA will support the research studies covered by this notice under section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

FDA is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national effort to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a hard copy of the ''Healthy People 2010'' objectives, vols. I and II, conference edition (B0074) for $22 per set, by writing to the Office of Disease Prevention and Health Promotion Communication Support Center (Center), P.O. Box 37366, Washington, DC 20013–7366. Each of the 28 chapters of ''Healthy People 2010'' is $2 per copy. Telephone orders can be placed at the Center on 301–468–5690. The Center also sells the complete conference edition in CD–ROM format (B0071) for $5. This publication also is available on the Internet at http://health.gov/healthypeople under ''Publications.''

The Public Health Service (PHS) strongly encourages all award recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

II. Research Goals and Objectives

Proposed projects designed to fulfill the specific objectives of the following requested project will be considered for funding. Applicants may submit more than one application. It should be emphasized that in the following project there is a particular desire to promote the development of surrogate agents and techniques to facilitate studies that will reliably predict the ability of treatments or manufacturing processes to inactivate the infectivity and biological activity of prions associated with the family of diseases known as TSE. None of the proposed projects should involve human research subjects that are not exempt from the Department of Health and Human Services (DHHS) regulations (45 CFR part 46) for the protection of human research subjects. The project and its objectives are as follows:

There are two objectives to this project. The first objective of this project is to develop proteinase resistant proteins that can serve as surrogates for

infectious prions associated with the family of TSE diseases. These proteinase resistant surrogate proteins must be suitable for reliably measuring the efficacy of treatments or manufacturing processes intended to inactivate the infectivity and biological activity of TSE-related prions. The second objective of this project is to devise a system that will demonstrate that the surrogates will accurately predict the efficacy of prion-targeted inactivation methods in the context of FDA-regulated foods, food additives, dietary supplements or cosmetics, or the equipment used to manufacture or process them. For example, the surrogates should be evaluated in a regulated product wherein processing helps assure the elimination of infectious prion particles, such as a gelatin-based model test system with potential applicability to a wide range of these FDA-regulated products. Theoretically, such a system could rely upon the ability to unfold beta sheets that are structurally more stable than prion protein to correlate surrogate performance with prion inactivation. Alternatively, a system may rely upon a direct demonstration of the correlation between surrogate performance and prion inactivation through the use of bioassays. Emphasis will be placed on creative solutions capable of both developing the desired surrogates and providing evidence of their performance.

III. Mechanism of Support

A. Award Instrument

Support for this program will be in the form of cooperative agreements. These cooperative agreements will be subject to all policies and requirements that govern the research grant programs of the PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 do not apply to this program. The NIH modular grant program does not apply to this FDA program.

B. Eligibility

These cooperative agreements are available to any foreign or domestic, public or private non-profit entity (including State and local units of government) and any foreign or domestic, for-profit entity. For-profit entities must commit to excluding fees or profit in their request for support to receive awards. Organizations described in section 501(c)(4) of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive awards.

C. Length of Support

The length of support will be for up to 4 years. Funding beyond the first year will be noncompetitive and will depend on:

1. Satisfactory performance during the preceding year, and

2. Availability of Federal FY funds.

IV. Reporting Requirements

Annual Financial Status Reports (FSR) (SF–269) are required. An original FSR and two copies shall be submitted to FDA's Grants Management Officer (see **ADDRESSES** section) within 90 days of the budget expiration date of the cooperative agreement. Failure to file the FSR on time may be grounds for suspension or termination of the agreement. Program Progress Reports will be required quarterly and will be due 30 days following each quarter of the applicable budget period except that the fourth quarterly report which will serve as the annual report will be due 90 days after the budget expiration date. For continuing agreements, an annual Program Progress Report is also required. Submission of the noncompeting continuation application (PHS 2590) will be considered as the annual Program Progress Report. The recipient will be advised of the suggested format for the Program Progress Report at the time an award is made. In addition, the principal investigator will be required to present the progress of the study at an annual FDA extramural research review workshop in Washington, DC. Travel costs for this requirement should be specifically requested by the applicant as part of their application. A final FSR, Program Progress Report, and Invention Statement, must be submitted within 90 days after the expiration of the project period, as noted on the Notice of Grant Award.

Program monitoring of recipients will be conducted on an ongoing basis and written reports will be reviewed and evaluated at least quarterly by the Project Officer and the Project Advisory Group. Project monitoring may also be in the form of telephone conversations between the Project Officer/Grants Management Specialist and the Principal Investigator and/or a site visit with appropriate officials of the recipient organization. A record of these monitoring activities will be duly made in an official file specific for each cooperative agreement and may be available to the recipient of the cooperative agreement upon request.

V. Delineation of Substantive Involvement

Inherent in the cooperative agreement award is substantive involvement by the awarding agency. Accordingly, FDA will have a substantive involvement in the programmatic activities of all the projects funded under this RFA. Substantive involvement may include, but is not limited to the following:

1. FDA will provide guidance and direction with regard to the scientific approach and methodology that may be used by the investigator.

2. FDA will participate with the recipient in determining and executing any: (a) Methodological approaches to be used, (b) procedures and techniques to be performed, (c) sampling plans proposed, (d) interpretation of results, and (e) microorganisms and commodities to be used.

3. FDA will collaborate with the recipient and have final approval on the experimental protocols. This collaboration may include protocol design, data analysis, interpretation of findings, coauthorship of publications, and the development and filing of patents.

VI. Review Procedure and Criteria

A. Review Method

All applications submitted in response to this RFA will first be reviewed by grants management and program staff for responsiveness. To be responsive, an application must: (1) Be received by the specified due date; (2) be submitted in accordance with sections III.B, VII, and VIII.A of this document; (3) not exceed the recommended funding amount stated in section I of this document; (4) address the specific requirements of the project stated in section II of this document; and (5) bear the original signatures of both the principal investigator and the institution's/organization's authorized official. If applications are found to be not responsive to this announcement, they will be returned to the applicant without further consideration.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application.

Responsive applications will also be subject to a second level of review by a National Advisory Council for concurrence with the recommendations made by the first level reviewers. Final funding decisions will be made by the Commissioner of Food and Drugs or his designee.

B. Review Criteria

Applications will be evaluated by program and grants management staff for responsiveness. Applications will be reviewed and ranked. Funding will start with the highest ranked application and additional awards will be made based on an application's standing within the review rankings. All questions of a technical or scientific nature should be directed to the CFSAN program staff, and all questions of an administrative or financial nature should be directed to the grants management staff. (See the **FOR FURTHER INFORMATION CONTACT** section of this document for addresses.)

All applications will be reviewed and scored on the following criteria:

1. Soundness of the scientific rationale for the proposed study and appropriateness of the study design and its ability to address all of the objectives of the RFA;

2. Availability and adequacy of laboratory facilities, equipment, and support services, e.g., bio-statistics computational support, databases, etc.;

3. Research experience, training, and competence of the principal investigator and support staff; and

4. Whether the proposed study is within the budget guidelines and proposed costs have been adequately justified and fully documented.

VII. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or the original and two copies of PHS 5161–1 (Rev. 7/00) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Maura Stephanos (see **ADDRESSES**). State and local governments may choose to use the PHS 398 application form in lieu of PHS 5161–1. The application receipt date is June 10, 2002. No supplemental or addendum material will be accepted after the receipt date. The outside of the mailing package and item 2 of the application face page should be labeled: ''Response to RFA FDA CFSAN–02–3.''

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal business hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.) NOTE: Do not send applications to the Center for Scientific Research, National Institutes of Health (NIH). Any application that is sent to NIH, and is then forwarded to FDA and not received in time for orderly processing will be deemed not responsive and returned to the applicant. Applications must be submitted via mail or hand delivery as stated previously. FDA is unable to receive applications electronically. Applicants are advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by NIH on its applications.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or PHS 5161–1 (Rev. 7/00). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address.

The face page of the application should reflect the request for applications number, RFA–FDA–CFSAN–02–3. Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001. The requirements requested on Form PHS 5161–1 were approved and assigned OMB control number 0348–0043.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of DHHS or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph,etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: April 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8777 Filed 4–10–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 99D–4575 and 99D–4576]

Guidance for Industry: Food Contact Substance Notification System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two final guidance documents entitled: ''Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations'' and ''Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations.'' These guidance documents are intended to provide guidance for industry regarding the preparation of food contact notifications (FCNs) and petitions for food contact substances (FCSs). FDA is providing these guidance documents as part of its implementation of the FCN process established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written or electronic comments on these guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the guidance documents to the Office of Food Additive Safety (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on these guidance documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. You also may request a copy of the guidance documents by electronic mail at OPAPMN@CFSAN.FDA.GOV, or by telephone to the Office of Food Additive Safety at 202–418–3087 (voice) or FAX