Dated: June 21, 2004.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 04–15274 Filed 7–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0257]

Determination of Regulatory Review Period for Purposes of Patent Extension; Neotame

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for neotame 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that food additive.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 food additives, the testing phase begins when a major health or environmental effects test involving the food additive begins and runs until the approval phase begins. The approval phase starts with the initial submission of a petition requesting the issuance of a regulation for use of the food additive and continues until FDA grants permission to market the food additive. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director 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), FDA's determination of the length of a regulatory review period for a food additive will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(2)(B).

FDA recently approved for marketing the food additive neotame. Neotame is a nonnutritive sweetener in food. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for neotame (U.S. Patent No. 5,480,668) from The NutraSweet Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this food additive had undergone a regulatory review period and that the approval of neotame represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for neotame is 3,143 days. Of this time, 1,503 days occurred during the testing phase of the regulatory review period, 1,640 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a major health or environmental effects test (''test'') involving this food additive was begun*: December 2, 1993. FDA has verified the applicant's claim that the test was begun on December 2, 1993.

2. *The date the petition requesting the issuance of a regulation for use of the additive (''petition'') was initially submitted with respect to the food additive under section 409 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 348)*: January 12, 1998. The applicant claims December 17, 1997, as the date the petition for neotame was initially submitted; however, FDA records indicate that the petition was submitted on January 12, 1998.

3. *The date the petition became effective*: July 9, 2002. FDA has verified the applicant's claim that the regulation for the additive became effective/commercial marketing was permitted on July 9, 2002.

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, this applicant seeks 973 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by September 7, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 3, 2005. 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 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 21, 2004.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 04–15275 Filed 7–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support the National Alliance for Hispanic Health; Notice of Intent to Accept and Consider a Single Source Application; Availability of Funds for Fiscal Year 2004

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its

intent to accept and consider a single source application (RFA–FDA–OC–04–01) for the awarding of a Cooperative Agreement to the National Alliance for Hispanic Health (the Alliance). The purpose of the agreement is to empower consumers to improve their health by providing better consumer health information; ensure that health information available to consumers is clear, informative, and effective; leverage opportunities to eliminate health disparities in subpopulations; respond to the health promotion and disease prevention objectives of the Department of Health and Human Services (HHS) ''Healthy People 2010'' document; and improve health literacy for Hispanic Americans. FDA anticipates providing $65,000 (direct and indirect costs) in fiscal year (FY) 2004 in support of this project. Subject to the availability of funds and successful performance, 2 additional years of support up to $65,000 per year (direct and indirect) will be available.

DATES: Submit applications by August 6, 2004.

ADDRESSES: Submit completed applications to Sheila Gale, Division of Contracts and Grants Management (HFA–531), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7109, FAX: 301–827–7101, or e-mail: *sgale@oc.fda.gov*. If the application is hand-carried or commercially delivered, it should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857. Applications will be accepted during normal business hours, 8 a.m. to 4:30 p.m., Monday through Friday.

The application forms are also available either from Sheila Gale (see **ADDRESSES**) or via the Internet at *http://grants.nih.gov/grants/funding/phs398/phs398/html*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) Do not send the application to the Center for Scientific Research, National Institutes of Health (NIH). An application not received by FDA in time for orderly processing will be returned to the applicant without consideration. Please note that FDA is unable to receive applications electronically.

FOR FURTHER INFORMATION CONTACT:

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

Regarding the programmatic aspects: Mary C. Hitch, Office of External Relations (HF–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4406, or e-mail: *mhitch@oc.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing its intention to accept and consider a single source application from the Alliance for the support of a cooperative agreement to improve the health of the American Hispanic population by providing better consumer health information and ensuring the health information available to this consumer group is clear, informative, and effective. FDA authority to enter into grants and cooperative agreements is set out in section 1704 of the Public Health Service Act (42 U.S.C. 300u-3). This program is described in the Catalog of Federal Domestic Assistance No. 93.245. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public. This application is not subject to review under Executive Order 12372, Intergovernmental Review of Federal Programs (45 CFR part 100).

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 improve quality of life. Applicants may obtain a paper copy of the ''Healthy People 2010'' objectives, volumes I and II, for $70 ($87.50 foreign) S/N017–000–00550–9, by writing to the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Telephone orders can be placed to 202–512–2250. The document is also available in CD–ROM format, S/N/017–001–00549–5 for $19 ($23.50 foreign) as well as on the Internet at *http://www.healthypeople.gov* under ''Publications.''

II. Background

The Alliance, a nonprofit entity as described in section 501(c)3 of the Internal Revenue Code of 1968, is the oldest and largest network of Hispanic health and human service providers for the target population. The Alliance is an umbrella organization that serves more than 400 national and community-based organizations and other health professionals who deliver quality health and human services to more than 12 million Hispanic health consumers every year. The Alliance is a recognized leader within Hispanic communities and works with foundations, corporations, government agencies, universities, and private industry in carrying out its mission with the objective of improving the health status of Hispanic and minority populations.

For 30 years, the Alliance has been an active partner with FDA and its efforts to meet the FDA's mission in Hispanic communities. The Alliance has been extensively involved in FDA programs by serving on FDA advisory committees as consumer and health professional representatives. The Alliance partnered with FDA in the development, translation, adaptation, and distribution of consumer educational campaign materials. These bilingual (Spanish and English) materials have included: Video and print materials on nutrition labeling such as *Para Vivir Bien*, video and print materials on medication safety such as *Las Medicinas y Usted*, and development of a bilingual (Spanish and English) section for Hispanic consumers on the FDA Web site.

The Alliance worked with FDA in support of HHS' Hispanic Agenda for Action. The Alliance also worked with FDA and other U.S. Public Health Service (PHS) agencies to coordinate and manage the largest Hispanic health conference—The 1997 Health and Human Services National Hispanic Health Symposium. The symposium brought together over 500 Hispanic leaders and community-based organizations to develop a framework to involve Hispanic Americans in HHS programs. The Alliance also worked with FDA to tailor outreach programs in coordination with Hispanic to disseminate health information to the Hispanic community.

The Alliance has shown the unique capacity to work with academic institutions and health agencies on common education, service, and research endeavors focused on disease prevention and health promotion for minority, disadvantaged, and limited English proficient populations.

III. Delineation of Substantive Involvement

Inherent in the cooperative agreement award is substantive involvement by the awarding agency. Accordingly, FDA will have substantive involvement in the programmatic activities of the entire project funded by this cooperative agreement. Substantive involvement includes, but is not limited, to the following items:

1. FDA will appoint a project officer or coproject officer, who will actively monitor the FDA-supported program under this award.

2. FDA will provide guidance, direction and technical assistance in developing the approach and methods that may be used by the recipient.

3. FDA will participate with the recipient to determine the scope of: (1) Consumer health literacy educational

electronic media and Web campaigns; (2) the design and development of consumer health literacy publications; (3) the methodology, scope, and interpretation of focus groups pre- and post-test health literacy messages; and (4) the utility of current consumer health literacy education materials.

4. FDA will have final approval of the methodology for behavioral research studies on disparities in health for Hispanic Americans, including protocol design, data analysis, interpretation of findings, and coauthorship of publications.

IV. Goals and Objectives

Through this cooperative agreement FDA seeks to support initiatives that will reach millions of consumers within the targeted population with credible health information by conducting culturally and linguistically appropriate public education initiatives through print and electronic media, help lines, the Internet, libraries, publication of bilingual patient and consumer health information materials (English and Spanish) and networks of community-based organizations.

V. Availability of Funds

It is anticipated that FDA will fund this cooperative agreement at a level of $65,000 (direct and indirect costs) for the first year award.

VI. Length of Support

The length of support will be 1 year with the possibility of an additional 2 years of noncompetitive support. Continuation beyond the first year will be based upon satisfactory performance during the preceding year, receipt of a noncompeting continuation application, and the availability of Federal FY appropriations.

VII. Reason for Single Source Selection

FDA believes that there is compelling evidence that the Alliance is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. The Alliance is an established and recognized authority on Hispanic American health, health disparities, and health literacy needs. The Alliance has shown a unique capacity to enhance health literacy. The Alliance has accomplished the following:

• Developed a nationally recognized center for health information for health professionals and Hispanic consumers. The center includes development and operation of a toll-free national bilingual (Spanish and English) telephone help line that provides health information to callers, drawing from a regularly updated resource of over 16,000 community health providers. The center also reviews bilingual health information materials for accuracy and timeliness;

• Provided valuable information and leadership through their trademark Provider Information Training and Technical Assistance Network program. This program trains health care professionals on how to work more effectively with minority, disadvantaged and limited English proficient populations;

• Established a capacity to deliver family-focused services to Hispanic communities, including the trademarked Strengthening Families bilingual family support and health education program;

• Developed a substantial portfolio of health promotion and disease prevention programs that deal extensively with Hispanic health issues within local communities. Through this initiative, the Alliance supports a network of local agencies that: Provide a foundation on which to develop, promote, and conduct community-based education; support health professional programs aimed at preventing and reducing unnecessary morbidity and health disparities among Hispanic populations. These initiatives support the HHS ''Healthy People 2010'' goals;

• Assessed and evaluated the current education, research, and disease prevention and health promotion programs for member organizations, affiliated groups and Hispanic subpopulations;

• Developed a critical knowledge base of essential disease prevention, health promotion, and research evaluation strategies that are necessary for any health intervention dealing with Hispanic Americans;

• Developed a national organization whose members have the collective capacity to conduct sponsored research;

• Reached millions of consumers within the targeted population with credible health information by conducting culturally and linguistically appropriate public education initiatives such as: (1) A national health information telephone help line; (2) an interactive health Web site that features Web broadcasts of Spanish language radio shows on Hispanic health topics; (3) an extensive bilingual consumer library; (4) publication of bilingual patient and consumer health information materials (English and Spanish); and (5) outreach through the Alliance Reporter (the official national newsletter) and a network of community media (television, radio, and print) and organizations;

• Supported health care providers in their efforts to deliver quality services by providing guidance on social service needs such as translation services, cultural proficiency education, and professional development on meeting the unique health needs of Hispanics;

• Supported a database of community-based organizations, health care providers and researchers with the capacity to reach and meet the needs of Hispanics in the United States; and

• Improved and promoted scientific research by collecting and upgrading proprietary health data.

VIII. Submission Requirements

The original and two copies of the completed grant application form PHS 398 (rev. 5/01) with copies of the appendices for each of the copies should be delivered to Sheila Gale (see **ADDRESSES**). The outside of the mailing package should be labeled ''Response to RFA–FDA–OC–04–1''. No supplemental or addendum material will be accepted after the receipt date. Information collection requirements requested on Form PHS 398 and the instruction have been submitted by the PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–001.

Data and information included in the application, if identified by the applicant as trade secret or confidential commercial information will be given treatment as such to the extent permitted by the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

IX. Reporting Requirements

An annual Standard Form (SF) 269, Financial Status Report (FSR), is required. An original and two copies of the Standard Form 269, Financial Status Report (FSR), must be submitted within 90 days after the end of the budget period. An original and two copies of the progress reports must be submitted on a quarterly basis no later than 30 days after each quarter. An annual progress report is also required. The noncompeting continuation application (PHS2590) will be considered the annual program progress report. A final program progress report, FSR, and invention statement must be submitted within 90 days after expiration of the project period of the cooperative agreement.

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. The application should specifically request travel costs

for this requirement in the budget section of the application.

X. Review Procedures and Evaluation Criteria

A. Review Procedures

The application submitted by the Alliance will initially be reviewed by grants management and program staff for responsiveness. To be considered, an application must meet the following requirements: (1) Be received by the specified due date; (2) be submitted in accordance with section VIII ''Submission Requirements'' of this document; (3) not exceed the $65,000 (direct and indirect) for each year requested; (4) address the specific program goals and objectives; and (5) bear the original signatures of both the principal investigator and the organization's authorized official. The application will be considered nonresponsive if it is not in compliance with this document. If the application is found to be nonresponsive, the application will be returned to the applicant without further consideration.

The application submitted by the Alliance will undergo a dual peer review. The application will be reviewed first for scientific and technical merit by an ad hoc panel of experts in areas associated with consumer health information and promotion and disease prevention. If the application is recommended for approval, it will then be presented to the National Advisory Environmental Health Sciences Council for their concurrence.

B. Review Criteria

The application will be reviewed and evaluated according to the following criteria:

Factor 1: Background (15 percent)

Applicant: (1) Demonstrated knowledge of the health literacy problem and health care needs in the Hispanic community; (2) documented outcomes of past efforts with the target population; and (3) proposed geographic locations to be served by the proposed program.

Factor 2: Approach (45 percent)

Applicant: (1) Describes an acceptable plan of action with details on how the proposed work will be performed, including a timeline, listing of other involved organizations, consultants and key individuals who will work on the project and a short description about their efforts or contributions to the proposed program; (2) identifies the results and benefits to be gained by the Hispanic community; (3) describes the expected program contributions from providing suitable health information toward improving health literacy and eliminating health disparities in the Hispanic community; and (4) describes how the proposed program meets the following proposed objectives:

• To empower consumers to improve their health by providing better health information; and

• To ensure that health information is clear, informative, effective, and accessible by the Hispanic community.

Factor 3: Management Plan (20 percent)

Applicant's demonstrated capability to manage the program as determined by the following: (1) Qualification and experience of proposed staff or requirements for ''to be hired'' staff, proposed staff effort, management experience of the organization related to the proposed program; (2) support and established network to conduct the proposed program; and (3) evaluate the program as determined by the thoroughness, feasibility and appropriateness of the proposed program evaluation design, and data collection and analysis procedures.

Factor 4: Budget and Budget Justification (20 Points)

Applicant: Proposed program costs are reasonable and based on activities to be carried out and the expected program outcomes.

XI. Mechanism of Support

Support for this project will be in the form of a cooperative agreement. This agreement 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, 45 CFR part 74, and PHS Grants Policy Statement. The regulations issued under Executive Order 12372 do not apply. The length of support will be up to 3 years. Cost sharing or matching is not a requirement of this program. The NIH modular grant program does not apply to this FDA program.

XII. Dun and Bradstreet Number (DUNS) Requirement

Beginning October 1, 2003, applicants are required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. To obtain a DUNS number, call 1–866–705–5711. Be certain to identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

XIII. Legend

Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552) as determined by HHS freedom of information officials 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 the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: June 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15427 Filed 7–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Division of Perinatal Systems and Women's Health—Forms for the Guidance for Application and Other Reports—NEW

The *Application Guidance for grants within the Division of Perinatal Systems and Women's Health (DPSWH)* is used annually by all community based organizations and agencies applying for