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 INFUSE BONE GRAFT/LT–CAGE LUMBAR TAPERED FUSION DEVICE is 2,052 days. Of this time, 1,515 days occurred during the testing phase of the regulatory review period, while 537 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: November 20, 1996. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective November 20, 1996.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: January 12, 2001. FDA has verified the applicant's claim that the premarket approval application (PMA) for INFUSE BONE GRAFT/LT–CAGE LUMBAR TAPERED FUSION DEVICE (PMA P000058) was initially submitted January 12, 2001.

3. *The date the application was approved*: July 2, 2002. FDA has verified the applicant's claim that PMA P000058 was approved on July 2, 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 applications for patent extension, this applicant seeks 463 days of patent term extension for U.S. Patent No. 5,984,967 or 347 days of patent term extension for U.S. Patent No. 5,782,919.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 29, 2007. 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 September 24, 2007. 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: March 12, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–5635 Filed 3–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Chicago District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA-regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop is scheduled for May 16, 2007, from 8:30 a.m. to 5 p.m. and May 17, 2007, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the Oak Brook Hills Marriott Resort, 3500 Midwest Rd., Oak Brook, IL 60523, 630–850–5555, FAX: 630–850–5569.

Contact: Marie Falcone, Food and Drug Administration, U.S. Customhouse, 200 Chestnut St., rm. 900, Philadelphia, PA 19106, 215–717–3703, FAX: 215–597–5798, e-mail: *marie.falcone@fda.hhs.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $575 (member), $650 (nonmember), or $525 (Federal Government employee nonmember). (Registration fee for nonmembers includes a 1-year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, 530 West Butler Ave., suite 109, Chalfont, PA, 18914. To register via the Internet go to *www.socra.org* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800–SoCRA92 (800–762–7292), or 215–822–8644, or via e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at the Oak Brook Hills Marriott Resort, at the reduced conference rate, contact the Oak Brook Hills Marriott Resort (see *Location*) before April 24, 2007, citing meeting code SCRSCRA. The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials.

Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact Marie Falcone (see *Contact*) at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The workshop on FDA clinical trials statutory and regulatory requirements helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion include the following: (1) FDA regulation of the conduct of clinical research; (2) medical device, drug, biological and food product aspects of clinical research; (3) investigator initiated research; (4) pre-investigational new drug application meetings and FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of institutional review boards; (8) electronic records requirements; (9) adverse event reporting; (10) how FDA conducts bioresearch inspections; and (11) what happens after the FDA inspection. FDA

has made education of the research community a high priority to ensure the quality of clinical data and protect research subjects. The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: March 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–5633 Filed 3–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

American Indians into Psychology; Notice of Competitive Grant Applications for American Indians Into Psychology Program

Announcement Type: New.

Funding Opportunity Number: HHS–IHS–2007–INPSY–0001.

CFDA Number: 92.970.

Key Dates:

Application Deadline: May 7, 2007.

Application Review: May 30, 2007.

Application Notification: June 22, 2007.

Anticipated Award Start Date: August 1, 2007.

I. Funding Opportunity Description

The Indian Health Service (IHS) announces that competitive grant applications are being accepted for the American Indians into Psychology Program. This grant is established under the authority of ''25 U.S.C. 1621p(a–d).'', Indian Health Care Improvement Act, Pub. L. 94–437, as amended by Pub. L. 102–573. The purpose of the Indians into Psychology Program is to augment the number of Indian health professionals serving Indians by encouraging Indians to enter the health professions and removing the multiple barriers to their entrance into IHS and private practice among Indians. This program is described at 93.970 in the Catalog of Federal Domestic Assistance. Costs will be determined in accordance with applicable Office of Management and Budget Circulars. The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Health People 2010, a PHS-led activity for setting priority areas. This program announcement is related to the priority area of Educational and Community-based programs. Potential applicants may obtain a copy of Healthy People 2010, summary report in print, Stock No. 017–001–00547–9, or via CD–ROM, Stock No. 107–0017–00549–5, through the Superintendent of Documents, Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250–7945, (202) 512–1800. You may access this information via the Internet at the following Web site: *http://www.health.gov/healthypeople*

The Public Health Service strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Pub. L. 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

II. Award Information

Type of Awards: Grant.

Estimated Funds Available: the total amount identified for Fiscal year 2007 is $246,332. The award is for 12 months in duration and the average award is approximately $246,322. Awards under this announcement are subject to the availability of funds.

Anticipated Number of Awards: An estimated 1 award will be made under the program. If funding becomes available, additional awards may be made.

Project Period: 36 months.

Award Amount: $246,322, per year.

III. Eligibility Information

1. Eligible Applicants:

Public and nonprofit private colleges and universities are eligible to apply for a grant. However, only one grant will be awarded and funded to a college or university per funding cycle.

2. Cost Sharing/Matching:

This announcement does not require matching funds or cost sharing.

3. Other Requirements:

Required Affiliations—The grant applicant must submit official documentation indicating a Tribe's cooperation with and support of the program within the schools on its reservation and its willingness to have a Tribal representative serving on the program advisory board. Documentation must be in the form prescribed by the Tribe's governing body, i.e., letter of support or Tribal resolution. Documentation must be submitted from every Tribe involved in the grant program. If application budgets exceed the stated dollar amount that is outlined within this announcement it will not be considered for funding.

IV. Applicant and Submission Information

1. Applicant package may be found in Grants.gov (*www.grants.gov*) or at *http://www.ihs.gov/NonMedicalPrograms/gogp/gogp_funding.asp*. Information regarding the electronic application process may be directed to Michelle G. Bulls, at (301) 443 6528 or *Michelle-Bulls@ihs.gov*. The entire application package is available at: *http://www.grants.gov/Apply*. Detailed application instructions for this announcement are downloadable on *www.Grants.gov*

2. Content and Form of Application Submission:

- Be single spaced.
- By typewritten.
- Have consecutively numbered pages.
- Use black type not smaller than 12 characters per one inch.
- Contain a narrative that does not exceed 7 typed pages that includes the other submission requirements below. The 7 page narrative does not include the work plan, standard forms, Tribal resolutions or letters of support (if necessary), table of contents, budget, budget justifications, narratives, and/or other appendix items.

Public Policy Requirements: All Federal-wide public policies apply to IHS grants with the exception of Lobbying and Discrimination.

3. Submission Dates and Times:

Applications must be submitted electronically through Grants.gov by 12 midnight Eastern Standard Time (EST). If technical challenges arise and the applicant is unable to successfully complete the electronic application process, the applicant should contact Michelle G. Bulls, Grants Policy Staff, fifteen days prior to the application deadline and advise of the difficulties that your organization is experiencing. The grantee must obtain prior approval, in writing (e-mails are acceptable) allowing the paper submission. If submission of a paper application is requested and approved, the original and two copies may be sent to the appropriate grants contact that is listed in Section IV above. Applications not