Silver Spring, MD 20993–0002, 301–796–0175.

Regarding the ICH

Michelle Limoli, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 3506, Silver Spring, MD 20993–0002, 301–796–4600.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory Agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of March 26, 2008 (73 FR 16024), FDA published a notice announcing the availability of a draft guidance entitled ''S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use.'' The notice gave interested persons an opportunity to submit comments by May 12, 2008.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory Agencies in November 2011.

The purpose of the ICH S2(R1) revision is to provide guidance on optimizing the standard genetic toxicology battery for prediction of potential human risks, and on interpreting results, with the goal of improving risk characterization for carcinogenic effects that have their basis in changes in the genetic material. The revised guidance describes internationally agreed-upon standards for followup testing and interpretation of positive results in vitro and in vivo in the standard genetic toxicology battery, including assessment of nonrelevant findings.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: June 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–13774 Filed 6–6–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of a Noncompetitive Supplement and a 7-Month Extension of the Period of Support for the Frontier Extended Stay Clinic (FESC) Cooperative Agreement Recipient—SouthEast Alaska Regional Health Consortium

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of a Noncompetitive Supplement and a 7-Month Extension of the Period of Support for the Frontier Extended Stay Clinic (FESC) Cooperative Agreement Recipient—SouthEast Alaska Regional Health Consortium.

SUMMARY: The Health Resources and Services Administration (HRSA) will be issuing a non-competitive supplement and a 7-month extension of the period of support to the Frontier Extended Stay Clinic (FESC) Cooperative Agreement recipient of record, SouthEast Alaska Regional Health Consortium (Grant Number U17RH23237). The FESC Cooperative Agreement helps to examine the effectiveness and appropriateness of a new type of provider, FESC, in providing health care services in remote areas. The 7-month extension with funds will align with the related three-year Centers for Medicare and Medicaid Services (CMS) demonstration, which will run until March 2013.

SUPPLEMENTARY INFORMATION: The recipient of record and intended award amount is:

Grant No.	Grantee name	Grantee city	Grantee state	CFDA No.	Recommended supplemental award amount
U17RH23237	SouthEast Alaska Regional Health Consortium	Sitka	AK	93.912	$700,000.00

Intended Recipient of the Award: SouthEast Alaska Regional Health Consortium.

Amount of the Award: $700,000.00.

CFDA Number: 93.912.

Project Period: September 1, 2011 through March 31, 2013.

Authority: Section 330A of the Public Health Service Act, as amended, (42 U.S.C. 254c).

Justification

The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) authorized CMS to conduct a demonstration program in which FESCs would be treated as Medicare providers. The CMS demonstration took several years to develop and officially began on April 1, 2010, when the first clinic site submitted the first claim to CMS. This 3-year demonstration will run until March 2013.

In 2004, Congress appropriated funds to HRSA to undertake a demonstration project that supports the development of a FESC CMS Medicare provider type. By supplementing the award to the current recipient, there will be continued support to keep the FESC sites participating through (or close to) the end of the CMS demonstration. The CMS demonstration provides payments only for FESC services provided to Medicare beneficiaries. On average, only 20 percent of FESC services are Medicare-eligible, meaning that the clinics do not receive payment for as much as 80 percent of their FESC services. HRSA funds provide support for those services that are not reimbursed by Medicare.

FOR FURTHER INFORMATION CONTACT: Aaron Fischbach, Health Resources and Services Administration, Office of Rural Health Policy, 5600 Fishers Lane, Room 5A–05, Rockville, Maryland 20852, or email *afischbach@hrsa.gov.*

Dated: May 30, 2012.

Mary K. Wakefield,

Administrator, Health Resources and Services Administration.

[FR Doc. 2012–13831 Filed 6–6–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Review of a K22 Application.

Date: June 12, 2012.

Time: 5:30 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sergei Radaev, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8113, Bethesda, MD 20892, 301–435–5655, *sradaev@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/sep/sep.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 1, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–13837 Filed 6–6–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel Interdisciplinary Training and Education for Type 1 Diabetes Research (T90/R90).

Date: June 26, 2012.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *ls38z@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)