SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Suicidality: Prospective Assessment of Occurrence in Clinical Trials." The purpose of this guidance is to assist sponsors in prospectively assessing the occurrence of treatment-emergent suicidality in clinical trials of drug and biological products. Specifically, this guidance addresses FDA's current thinking regarding the importance of suicidality assessment in psychiatric and nonpsychiatric drug trials and the general principles for how best to accomplish this assessment during drug development.

The principles discussed in this guidance for the prospective assessment of suicidality involve actively querying patients about the occurrence of suicidal thinking and behavior, rather than relying on patients to report such occurrences spontaneously, followed by retrospective classification of events into appropriate categories. This guidance recommends a specific suicidality assessment instrument that can be used to conduct such prospective assessments and offers guidance on the use of alternative instruments. This guidance does not address the complex analytic issues involved in the analysis of the suicidality data that will be derived from prospective assessments of suicidality; these issues will be addressed in separate guidances.

Comments are welcome regarding the recommended approach of carrying out prospective suicidality assessments in all clinical trials for all drugs that are pharmacologically similar to isotretinoin and other tretinoins, beta blockers (especially those entering the brain), reserpine, drugs for smoking cessation, and drugs for weight loss for which possible signals of risk for suicidality have already been identified.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the prospective assessment of suicidality occurrence in clinical trials. 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 comments. It is no longer necessary to send two copies 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 either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: September 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–22404 Filed 9–8–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Child Health and Human Development Special Emphasis Panel; Neonatal Research Network.

Date: October 5–6, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Legacy Hotel and Meeting Center, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Rita Anand, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301–496–148, *anandr@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 2, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–22499 Filed 9–8–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

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 meetings.

The meetings 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 patentablematerial, 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 on Aging Special Emphasis Panel; Aging and Distal Radius Fracture.

Date: October 7, 2010.

Time: 6 p.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20892.

Contact Person: Alicja L. Markowska, PhD, DSC, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–496–9666, *markowsa@nia.nih.gov*.

Name of Committee: National Institute on Aging Special Emphasis Panel; Aminergic Function in Brain Aging and Alzheimer's Disease.

Date: October 19, 2010.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *PARSADANIANA@NIA.NIH.GOV*.