

the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on [regulations.gov](http://www.regulations.gov) may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 13, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010-22394 Filed 9-8-10; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[ATSDR-265]

#### Development of Set 24 Toxicological Profiles

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (DHHS).

**ACTION:** Notice.

**DATES:** Profiles will be available to the public on or about October 17, 2010.

**SUMMARY:** The Agency for Toxic Substances and Disease Registry (ATSDR) of the Department of Health and Human Services is developing Set 24 Toxicological Profiles. Set 24 Toxicological Profiles consists of one new draft and one updated draft. Electronic access to these documents will be available at the ATSDR Web site: <http://www.atsdr.cdc.gov/toxpro2.html>.

#### Set 24 Toxicological Profiles

The following toxicological profiles are now being developed:

Toxicological profile	CAS number
Toxaphene .....	8001-35-2
Trichlorobenzene*	
1,2,3-Trichlorobenzene	87-61-6
1,2,4-Trichlorobenzene	120-82-1
1,3,5-Trichlorobenzene	108-70-3
Trichlorobenzene ....	12002-48-1

\* Denotes new profile.

**SUPPLEMENTARY INFORMATION:** The Superfund Amendments and Reauthorization Act of 1986 (42 U.S.C. 9601 *et seq.*) amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) (42 U.S.C. 9601 *et seq.*) by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA)

with regard to hazardous substances that are most commonly found at facilities on the CERCLA National Priorities List. Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the Priority List of Hazardous Substances (<http://www.atsdr.cdc.gov/cercla/07list.html>).

This list names 275 hazardous substances that pose the most significant potential threat to human health as determined by ATSDR and EPA. The availability of the revised list of the 275 priority substances was announced in the **Federal Register** on March 6, 2008 (73 FR 12178). For prior versions of the list of substances, see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744); November 17, 1997 (62 FR 61332); October 21, 1999 (64 FR 56792); October 25, 2001 (66 FR 54014); November 7, 2003 (68 FR 63098); and December 7, 2005 (70 FR 70284).

Notice of the availability of drafts of one updated and one new toxicological profile for public review and comment will be published in the **Federal Register** on or about October 17, 2010, with notice of a 90-day public comment period for each profile, starting from the actual release date. Following the close of the comment period, chemical-specific comments will be addressed, and where appropriate, revisions will be incorporated into each profile.

#### FOR FURTHER INFORMATION CONTACT:

Commander Jessilyn B. Taylor, Division of Toxicology and Environmental Medicine, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mail Stop F-62, Atlanta, GA 30333; telephone (770) 488-3313; e-mail: [JBTaylor@cdc.gov](mailto:JBTaylor@cdc.gov).

Dated: September 3, 2010.

Ken Rose,

Associate Director, Office of Policy, Planning and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

[FR Doc. 2010-22439 Filed 9-8-10; 8:45 am]

BILLING CODE 4163-70-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0451]

#### Draft Guidance for Industry on Suicidality: Prospective Assessment of Occurrence in Clinical Trials; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (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.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 8, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Thomas Laughren, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4114, Silver Spring, MD 20993-0002, 301-796-2260.

**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 tretinoin, 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](mailto: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]

**BILLING CODE 4140-01-P**

**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 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 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, [markowska@nia.nih.gov](mailto:markowska@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, [PARSADANIAN@NIA.NIH.GOV](mailto:PARSADANIAN@NIA.NIH.GOV).