

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

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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 (70FR 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.

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.