

hearing and are encouraged to arrive early to ensure the designated order of presentation times. We will try to accommodate all persons who wish to present; however, the duration of each speaker's testimony may be limited by time constraints. An agenda of the meeting and other background material will be made available 5 days before the meeting at <http://www.fda.gov/Drugs/NewsEvents/ucm326450.htm>.

Questions about the meeting may also be also submitted to IssuesWithOpioids@fda.hhs.gov prior to the February 7 and February 8, 2013, meeting dates.

The hearing is free and seating will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the numbers of participants from individual organizations as well as total number of attendees based on space limitations. Registrants will receive confirmation once they have been accepted to attend the hearing. For those who cannot attend in person, information regarding viewing a live Web cast of the public hearing will be located at: <http://www.fda.gov/Drugs/NewsEvents/ucm326450.htm>.

If you need special accommodations due to a disability, contact Elizabeth Giaquinto or Mary Gross (see **FOR FURTHER INFORMATION CONTACT**).

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10), subpart C). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

The hearing will be transcribed as stipulated in § 15.30(b). A transcript will be available for review at the Division of Dockets Management (see

ADDRESSES) and on the Internet at <http://www.regulations.gov> within 30 days of the meeting. A transcript will also be available in either hard copy or on CD-ROM after submission of a Freedom of Information request. Submit written requests to the Division of Freedom of Information (ELEM-1029), Office of Management Programs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

V. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments for consideration by April 8, 2013. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments so that they identify the specific questions to which they refer. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: December 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 USC, as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract

proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; N43DA13-4417: Video Gaming Targeting Relapse Prevention in Youth with Substance Use Disorders.

Date: January 9, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Nadine Rogers, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4229, MSC 9550, Bethesda, MD 20892-9550, 301-402-2105, rogersn2@nida.nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Profile Screening and Predictive Toxicology (8909).

Date: February 12, 2013.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892-9550, (301) 435-1439, lf33c.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: December 13, 2012.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

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