

Individuals who would like to participate via conference call may do so by dialing toll-free 888-469-0957, when prompted enter pass code: 8955387. Individuals whose full participation in the meeting will require special accommodations (e.g., sign language interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should notify Dr. MJ Karimi, PCPID Team Lead, via email at [MJ.Karimie@acl.hhs.gov](mailto:MJ.Karimie@acl.hhs.gov), or via telephone at 202-357-3588, no later than Monday, July 27, 2015. The PCPID will attempt to accommodate requests made after this date, but cannot guarantee the ability to grant requests received after the deadline. All meeting sites are barrier free, consistent with the Americans with Disabilities Act (ADA) and the Federal Advisory Committee Act (FACA).

*Agenda:* The Committee Members will discuss, finalize and approve the 2015 PCPID Report to the President. They will also begin exploring the topics for the next PCPID Report to the President.

**FOR FURTHER INFORMATION CONTACT:** For further information, please contact Dr. MJ Karimi, Team Lead, President's Committee for People with Intellectual Disabilities, One Massachusetts Avenue NW., Room 4206, Washington, DC 20201. Telephone: 202-357-3588. Fax: 202-205-8037. Email: [MJ.Karimie@acl.hhs.gov](mailto:MJ.Karimie@acl.hhs.gov)

**SUPPLEMENTARY INFORMATION:** The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and support for individuals with intellectual disabilities. The PCPID executive order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: June 24, 2015.

**Aaron Bishop,**

*Commissioner, Administration on Intellectual and Developmental Disabilities (AIDD).*

[FR Doc. 2015-16488 Filed 7-2-15; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-2270]

#### The Drug Supply Chain Security Act Implementation: Product Tracing Requirements for Dispensers—Compliance Policy; Guidance for Industry, Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “DSCSA Implementation: Product Tracing Requirements for Dispensers—Compliance Policy.” This guidance announces FDA’s intention with regard to enforcement of certain product tracing requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) added by the Drug Supply Chain Security Act (DSCSA). FDA does not intend to take action against dispensers who, prior to November 1, 2015, accept ownership of product without receiving product tracing information, prior to or at the time of a transaction or do not capture and maintain the product tracing information, as required by the FD&C Act.

**DATES:** Effective July 1, 2015. For information about enforcement dates, please see the **SUPPLEMENTARY INFORMATION** section.

**ADDRESSES:** All communications in response to this notice should be identified with Docket No. FDA-2015-D-2270, and should be directed to the office listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, [drugtrackandtrace@fda.hhs.gov](mailto:drugtrackandtrace@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

We are announcing the availability of a guidance for industry entitled “DSCSA Implementation: Product Tracing Requirements for Dispensers—Compliance Policy.” We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or

appropriate (21 CFR 10.115(g)(2)). We made this determination because this guidance document provides information pertaining to statutory requirements that take effect on July 1, 2015, regarding the provisions to provide and capture product tracing information under section 582(d)(1) of the FD&C Act (21 U.S.C 360eee-1(d)(1)). It is important that FDA provide this information before that date. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency’s good guidance practices (21 CFR 10.115(g)(3)).

On November 27, 2013, the DSCSA (Title II of Pub. L. 113-54) was signed into law. Section 202 of DSCSA adds sections 581 and 582 to the FD&C Act, which set forth new definitions and requirements for the tracing of products through the pharmaceutical distribution supply chain. Starting in 2015, trading partners (manufacturers, wholesale distributors, dispensers, and repackagers) are required under sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to exchange product tracing information when engaging in transactions involving certain prescription drugs. For dispensers, requirements for the tracing of products through the pharmaceutical distribution supply chain under section 582(d)(1) of the FD&C Act go into effect on July 1, 2015.

Some dispensers have expressed concern that electronic systems used to exchange, capture, and maintain product tracing information will not be operational by this effective date. Although the DSCSA allows product tracing information to be exchanged through paper in certain circumstances, FDA understands that many dispensers intend to utilize electronic systems to capture and maintain product tracing information. Thus, FDA recognizes that some dispensers may need additional time beyond July 1, 2015, to work with trading partners to ensure that the product tracing information required by section 582 is captured and maintained by dispensers. In light of these concerns, FDA does not intend to take action against dispensers who, prior to November 1, 2015: (1) Accept ownership of product without receiving product tracing information, prior to or at the time of a transaction, as required by section 582(d)(1)(A)(i) of the FD&C Act or (2) do not capture and maintain the product tracing information, as required by section 582(d)(1)(A)(iii) of the FD&C Act. This compliance policy does not extend to other requirements of the FD&C Act applicable to dispensers and other trading partners, including

those in section 582, such as verification related to suspect and illegitimate product (including quarantine, investigation, notification and recordkeeping) and requirements related to engaging in transactions only with authorized trading partners. The guidance document explains the scope of the compliance policy in further detail.

The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify all 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, and will be posted to the docket at <http://www.regulations.gov>.

## III. Electronic Access

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

Dated: June 29, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-16401 Filed 7-2-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Advisory Council on Alzheimer's Research, Care, and Services; Meeting

**AGENCY:** Assistant Secretary for Planning and Evaluation, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's

Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. During the July meeting, the Advisory Council will hear from experts on related dementias, such as Frontotemporal dementia, Lewy Body dementia, and others. Following this session, the Advisory Council will also hold a discussion of the expected bypass budget from NIA, required in the CROmnibus Bill. The Council will also discuss updates to international events on dementia.

**DATES:** The meeting will be held on April 28th, 2015 from 9:00 a.m. to 5:00 p.m. EDT.

**ADDRESSES:** The meeting will be held in the Great Hall in the Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

Comments: Time is allocated in the afternoon on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Rohini Khillan, OASPE, 200 Independence Avenue SW., Room 424E, Washington, DC 20201. Comments may also be sent to [napa@hhs.gov](mailto:napa@hhs.gov). Those submitting written comments should identify themselves and any relevant organizational affiliations.

**FOR FURTHER INFORMATION CONTACT:**

Rohini Khillan (202) 690-5932, [rohini.khillan@hhs.gov](mailto:rohini.khillan@hhs.gov). Note: Seating may be limited. Those wishing to attend the meeting must send an email to [napa@hhs.gov](mailto:napa@hhs.gov) and put "July 27 Meeting Attendance" in the Subject line by Friday, July 17, so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

**SUPPLEMENTARY INFORMATION:** Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

Topics of the Meeting: The Advisory Council will hear from experts on related dementias, such as Frontotemporal dementia, Lewy Body

dementia, and others. Following this session, the Advisory Council will also hold a discussion of the expected bypass budget from NIA, required in the CROmnibus Bill. The Council will also discuss updates to international events on dementia.

**Procedure and Agenda:** This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. The meeting will also be webcast at [www.hhs.gov/live](http://www.hhs.gov/live).

**Authority:** 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: June 26, 2015.

**Richard G. Frank,**

*Assistant Secretary for Planning and Evaluation.*

[FR Doc. 2015-16490 Filed 7-2-15; 8:45 am]

**BILLING CODE 4150-05-P**

## 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 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 Drug Abuse Special Emphasis Panel; R13 Conference Grant Review (PA 13-347).

**Date:** July 23, 2015.

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

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

**Contact Person:** Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4245, Rockville, MD 20852, 301-435-1426, [mcguireso@mail.nih.gov](mailto:mcguireso@mail.nih.gov).

**Name of Committee:** National Institute on Drug Abuse Special Emphasis Panel;