

found in brackets in the heading of this document. A copy of this notice and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: March 13, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8-5597 Filed 3-19-08; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0121]

#### Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information

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

**ACTION:** Notice; request for information.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting comments and information regarding technologies used for the identification, validation, tracking and tracing, and authentication of prescription drugs. This request is related to FDA's implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA).

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled "Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments."

**DATES:** Submit written or electronic comments and information by May 19, 2008.

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

**FOR FURTHER INFORMATION CONTACT:** Ilisa Bernstein, Office of Policy (HF-11),

Food and Drug Administration, 5600 Fishers Lane, rm. 14C-03, Rockville, MD 20857, phone: 301-827-3360, FAX 301-594-6777, e-mail: [ilisa.bernstein@fda.hhs.gov](mailto:ilisa.bernstein@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On September 27, 2007, FDAAA (Public Law 3580) was signed into law. Section 913 of this legislation requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. Specifically, section 913 created section 505D(b) of the Federal Food, Drug, and Cosmetic Act (the act), which directs the development of standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. Section 505D(b)(3) states that the standards developed under 505D "shall address promising technologies, which may include—(A) radio-frequency identification; (B) nanotechnology; (C) encryption technologies; and (D) other track and trace or authentication technologies."

FDA has previously identified counterfeit drugs as a threat to the safety of the public and the pharmaceutical supply chain.

1. In 2004, FDA's Counterfeit Drug Task Force issued a report (Task Force Report) on the threat of counterfeit medications and measures that can be taken by private and public stakeholders to make the U.S. drug supply chain more safe and secure. The 2004 Task Force Report stated, among other things, that:

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- Radio Frequency Identification (RFID) is a promising technology as a means to achieve e-pedigree; and
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007.

2. In 2006, the Task Force issued an update report which stated that the goal of widespread use of e-pedigree and track and trace technologies by 2007 would probably not be met. The voluntary approach taken did not provide enough incentives for the adoption and implementation of the technologies and e-pedigree.

As part of the efforts listed above, we received information about various technologies for the identification, track and trace, and authentication of prescription drugs, and we met with companies to learn more about these technologies. We are aware that significant progress has been made and new technologies are emerging for the identification, track and trace, and authentication of prescription drugs. In order to address the "promising technologies" related to standards development, as described in section 505D(b)(3) of the act, we are seeking information from technology vendors and others. Rather than meet individually with companies, for efficiency and to further our understanding and knowledge, we are requesting that information be submitted to the docket number listed above.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a related document entitled "Standards for Standardized Numerical Identifier, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments." Under section 505D(b)(1) and (b)(2) of the act, this related document seeks information from drug manufacturers, distributors, pharmacies, other supply chain stakeholders, foreign regulators, standards organizations, and other Federal agencies and interested parties on issues related to standards for identification, validation, tracking and tracing, and authentication for prescription drug products.

We are particularly interested in the following information regarding available and emerging technologies for identification, validation, track and trace, and authentication of prescription drugs:

1. What are the RFID technologies, encrypting technologies, and nanotechnologies that are relevant? What are other relevant technologies?

2. Please provide information related to:

- Strengths for identification, validation, track and trace, or authentication;
- Limitations for identification, validation, track and trace, or authentication;
- Costs of implementation and use;
- Benefits to the public health;
- Feasibility for widespread use;
- Utility for e-pedigree.

3. Is the technology interoperable with other technologies? If so, describe.

4. What standards are necessary for supply chain use of the specific technology? What is the status of development of such standards?

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and information. Submit a single copy of electronic comments and information or two paper copies of any mailed comments and information, except that individuals may submit one paper copy. Comments and information are to be identified with the name of the technology and the docket number found in brackets in the heading of this document. A copy of this notice and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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Dated: March 13, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8-5599 Filed 3-19-08; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Eye Institute Special Emphasis Panel, NEI Clinical Grant Applications.

*Date:* March 26, 2008.

*Time:* 2 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892. (Telephone Conference Call)

*Contact Person:* Houmam H. Araj, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, NIH, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892-9602, 301-451-2020, [haraj@mail.nih.gov](mailto:haraj@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Eye Institute Special Emphasis Panel, Secondary Data Analysis Grant Applications.

*Date:* March 28, 2008.

*Time:* 3 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892. (Telephone Conference Call)

*Contact Person:* Houmam H. Araj, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, NIH, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892-9602, 301-451-2020, [haraj@mail.nih.gov](mailto:haraj@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Eye Institute Special Emphasis Panel, NEI Epidemiology Grant Applications.

*Date:* April 1, 2008.

*Time:* 12 p.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health/NEI, 5635 Fishers Lane, Bethesda, MD 20892. (Telephone Conference Call)

*Contact Person:* Anne E. Schaffner, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892-9300, (301) 451-2020. [aes@nei.nih.gov](mailto:aes@nei.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Eye Institute Special Emphasis Panel, NEI Genetics and Genomics Applications.

*Date:* April 10, 2008.

*Time:* 12:30 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health/NEI, 5635 Fishers Lane, Bethesda, MD 20892. (Telephone Conference Call)

*Contact Person:* Anne E. Schaffner, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892-9300, (301) 451-2020, [aes@nei.nih.gov](mailto:aes@nei.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: March 13, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-5568 Filed 3-19-08; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

*Comments Are Invited On:* (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

*Proposed Project:* The Coordinating Center to Support State Incentive Grants to Build Capacity for Alternatives to Restraint and Seclusion (OMB No. 0930-0271) Revision.

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services has funded a Data Collection and Analysis for the Alternatives to Restraint and Seclusion Grant Program. This contract is an evaluation of SAMHSA's State Incentive Grants to Build Capacity for Alternatives to Restraint and Seclusion. These grants are designed to promote the implementation and evaluation of best practice approaches to reducing the use of restraint and seclusion in mental health facilities. Grantees consist of 8 sites (state mental health agencies), all of which will be implementing