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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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Certifier

A. Corbin

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 *[insert date 60 days after date of publication in the Federal Register]*.

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.

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.

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: 3/13/08
March 13, 2008.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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