Cincinnati Hilton Netherlands Plaza, 35 West 5th Street, Cincinnati, OH, 45202, 513–421–9100. To make reservations online, please visit the "Venue/Logistics" link at *http://www.XavierMedCon.com* to make reservations.

If you need special accommodations due to a disability, please contact Marla Phillips (see *Contact Persons*) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health. The conference will provide those engaged in FDA-regulated medical devices (for humans) with information on the following topics:

- Global compliance,
- Global approval process,
- Global harmonization,
- Recalls and corrections and removals,
- Common 483 observations,
- What happens after an inspection,
- Medical device reports,
- Regulatory impact of design and process changes,
- Integrating internal and external resources for clinical trials,
- New ways of doing biostatistics,
- Innovative clinical study design,
- Challenges in conducting global clinical trials,
- Comparison of design history file and dechnical dossier,
- Integrating risk management in device/combination products,
- Design controls: Human factors,
- Labeling and promotion,
- Corrective and preventive actions,
- International filing requirements,
- Promotion of device prior to approval,
- Combination product filings—tips for successful application,
- The role of information technology in clinical trials and post-approval process,
- Bioresearch monitoring early intervention initiatives for electronic records, and
- Handling images and other non-traditional electronic data.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) by providing outreach activities by Government agencies to small businesses.

Dated: March 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6865 Filed 3–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0001]

Guidance for Industry on Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Standards for Securing the Drug Supply Chain-Standardized Numerical Identification for Prescription Drug Packages." This guidance is being issued under the Federal Food, Drug, and Cosmetic Act (the act), which requires FDA to develop standards for standardized numerical identifiers for prescription drugs.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Docket Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Ilisa B.G. Bernstein, Office of the Commissioner/Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4840, e-mail: *ilisa.bernstein@fda.hhs.gov*;

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210; or

Meredith Francis, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3476, email: *Meredith.frances@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Standards for Securing the Drug Supply Chain-Standardized Numerical Identification for Prescription Drug Packages." In the **Federal Register** of January 16, 2009 (74 FR 3054), a draft version of this guidance was made available for public comment.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85) was signed into law. Section 913 of this legislation created section 505D of the act, which 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. Section 505D of the act directs the Secretary to consult with specific entities to prioritize and develop standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. The statute also directs that no later than 30 months after the date of enactment of FDAAA, the Secretary shall develop a standardized numerical identifier (SNI) to be applied to a prescription drug at the point of manufacturing and repackaging at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug. An SNI applied

at the point of repackaging is to be linked to the SNI applied at the point of manufacturing, and to the extent practicable, the SNI should be harmonized with international consensus standards for such an identifier (see section 505D(b)(2) of the act). The provisions in section 505D(b) of the act complement and build on FDA's longstanding efforts to further secure the U.S. drug supply.

The agency received 44 comments in response to our request for public comment on the draft guidance. FDA also sought public comment on specific questions related to development of an SNI by opening a docket to receive information (73 FR 14988, March 20, 2008). We received 59 comments from a range of stakeholders, including manufacturers, wholesalers, pharmacies, trade and health professional organizations, technology vendors, health professionals, consumers, and State governments. We also shared both of these requests with State governments, other Federal agencies, and with foreign governments. The standards included in this guidance are based on information received in response to these requests for comment and the agency's familiarity with identification standards already in use for certain prescription biologics. All of the comments that we received have been considered and the guidance has been revised as appropriate.

The guidance is intended to be the first of several guidances and regulations that FDA may issue to implement section 505D of the act and its issuance is intended to assist with the development of standards and systems for identification, authentication, and tracking and tracing of prescription drugs. The guidance defines SNI for package-level identification only. For the purpose of this guidance, FDA considers the package to be the smallest unit placed into interstate commerce by the manufacturer or the repackager that is intended by that manufacturer or repackager, as applicable, for individual sale to the pharmacy or other dispenser of the drug product. Evidence that a unit is intended for individual sale, and thus constitutes a separate "package" for purposes of this guidance, would include evidence that it is accompanied by labeling intended to be sufficient to permit its individual distribution. This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The guidance does not address how to link a repackager SNI to a manufacturer SNI, nor does it address standards for prescription drug SNI at levels other than the package-level including, for example, the case and pallet levels. Standards for track and trace, authentication, and validation are also not addressed in this guidance because this guidance only addresses the standardized numerical identifier itself and not implementation or application issues.

The guidance represents the agency's current thinking on standards for drug supply chain security-standardized numerical identification for prescription drug packages. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information regarding labeling requirements for expiration date and lot numbering in 21 CFR. §§ 211.130, 211.137, 201.17, and 201.18 have been approved under OMB Control No. 0910–0139, and in §§ 610.60 and 610.61 have been approved under OMB Control No. 0910–0338.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. Electronic Access

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

Dated: March 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6863 Filed 3–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; Report of an Altered System of Records

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of an Altered System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the Health Resources and Services Administration (HRSA) is publishing notice of a proposal to alter the system of records for Health Professions Planning and Evaluation (SORN #09–15–0046; 63FR14124).

The purpose of these alterations is to change the name, to update addresses, authority for maintenance, to improve clarity and to add a new routine use. The routine use is to allow the Department to use information in the system of records for responding to potential breaches to the security or confidentiality of records in the system. These changes will have no known or perceived adverse effects on individual privacy.

DATES: HRSA filed an altered system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on March 1, 2010. To ensure all parties have adequate time in which to comment, the altered systems, including the routine uses, will become effective 30 days from the publication of the notice or 40 days from the date it was submitted to OMB and Congress, whichever is later, unless HRSA receives comments that require alterations to this notice.

ADDRESSES: Please address comments to Associate Administrator, Health Resources and Services Administration, 5600 Fishers Lane, Room 9A–18, Rockville, Maryland 20857. Comments received will be available for inspection at this same address from 9 a.m. to 3