

grantees that include Nonprofit organizations and State, Local and Tribal Governments. The evaluation for each program will be designed to assess progress and measure increased organizational capacity of grantees in

each of the two SCF programs. The purpose of this request will be to establish the approved baseline instruments for follow-up data collection.

*Respondents:* SCF Grantees (both the Nonprofit Capacity Building Program and the Government Capacity Building Program) made up of State, local, and Tribal governments, as well as nonprofit organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Nonprofit Capacity Building Program Performance Progress Report (PPR) ..	35	4	1	140
Government Capacity Building Program PPR .....	49	4	1	196

Estimated Total Annual Burden Hours: 336.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 24, 2010.

**Robert Sargis,**

Reports Clearance Officer.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0001]

**Food and Drug Administration/Xavier University Global Medical Device Conference**

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

**ACTION:** Notice of public conference.

**SUMMARY:** The Food and Drug Administration (FDA) Cincinnati District, in co-sponsorship with Xavier University, is announcing a public conference entitled "FDA/Xavier University Global Medical Device Conference." This 3-day public conference includes presentations from key FDA officials, global regulators, and industry experts. The public conference has three separate tracks of interest for quality, regulatory affairs, and clinical research professionals, and is intended for companies of all sizes and employees at all levels.

**Dates and Times:** The public conference will be held on May 5, 2010, from 8 a.m. to 5 p.m.; May 6, 2010, from 8 a.m. to 5 p.m.; and May 7, 2010, from 8 a.m. to 1 p.m.

**Location:** The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3396.

**Contact Persons:**

*For information regarding this notice:*

Gina Brackett, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513-679-2700, ext 167, FAX: 513-679-272, e-mail: [gina.brackett@fda.hhs.gov](mailto:gina.brackett@fda.hhs.gov).

*For information regarding the conference and registration:*

Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073, e-mail: [phillipsm4@xavier.edu](mailto:phillipsm4@xavier.edu).

*Registration:* There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, dinners, and dinner speakers for the 3 days of the conference. Early registration ends April 5, 2010. Standard registration ends May 4, 2010. There will be onsite registration. The cost of registration is as follows:

TABLE 1.—REGISTRATION FEES<sup>1</sup>

Attendee	Fee by April 5th	Fee by May 4th
Industry	\$995	\$1,200
Small Business (<100 employees)	\$800	\$1,000
Academic	\$600	\$700
Student	\$200	\$250
FDA Employee	Fee Waived	Fee Waived

<sup>1</sup> The fourth registration from the same company is free.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the "Registration" link on the conference Web site at <http://www.XavierMedCon.com>. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, e-mail, and payment information for the fee to Xavier University, Attention: Sue Bensman, 3800 Victory Parkway, Cincinnati, OH 45207. An e-mail will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown

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 technical 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.*

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## 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](mailto: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](mailto: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