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.


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. 35, 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 the repackager SNI to the
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
umerical 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
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–
0336.

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/Biologics
BloodVaccines/Guidance
ComplianceRegulatoryInformation/
Guidances/default.htm, or http://
www.regulations.gov.