studies. In coordination with the Office of Planning, Research and Evaluation, DPPE coordinates ANA's performance goals.

Dated: January 9, 2009.

Daniel C. Schneider,

Acting Assistant Secretary for Children and Families.

[FR Doc. E9–983 Filed 1–15–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0001]

Draft Guidance for Industry on Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages.'' This draft guidance is being issued under the Federal Food, Drug, and Cosmetic Act (the act), which requires FDA to develop standardized numerical identifiers for prescription drugs. We are also requesting responses from interested stakeholders to questions posed in this **Federal Register** notice related to the draft guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 16, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 to 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. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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, e-mail: *Stephen.ripley@fda.hhs.gov*;

Jennifer Devine, Center for Drug Evaluation and Research, 10903 New Hampshire Ave.,Silver Spring, MD 20993–0002, 301–796–3347, e-mail: *Jennifer.devine@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Draft Guidance for Industry on Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages.'' 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 identification, validation, authentication, and tracking and tracing of prescription drugs. No later than 30 months after the date of enactment of FDAAA, the statute also directs the Secretary to 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.

FDA sought public comment on specific questions related to development of an SNI. 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. The standards included in this draft guidance are based on information received in response to our request for comment and the agency's familiarity with identification standards already in use for certain prescription biologics.

This draft guidance addresses only package-level SNI. Linking of a repackager SNI to a manufacturer SNI is not addressed in this guidance. Additionally, standards for track and trace, authentication, and validation are not included in this guidance. This draft guidance is intended to be the first of several guidances and regulations that FDA may issue to implement section 505D of the act; issuance of this guidance is intended to assist with the development of standards and systems for identification, authentication, and tracking and tracing of prescription drugs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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. Request for Information

To assist us in finalizing the draft guidance and aid us in future guidance development and rulemaking related to section 505D of the act, we are seeking responses from interested stakeholders on the following questions. We also

welcome comment on any aspect of the draft guidance.

1. We believe that the serialized National Drug Code (sNDC) described in the draft guidance is appropriate for package level identification for most prescription drugs; however, it might not be useful at the pallet or other intermediate level, such as the case. We did not receive many comments related to standards for numerical identification at the case or pallet level and would like broader input on this subject. Please comment on whether there are any standards that would be appropriate for serialization or other numerical identification at the case or pallet level.

2. Some comments recommended that the SNI allow for alpha-numeric serial numbers in order to increase the choices for the numbers. FDA's draft guidance recommends that the SNI for most prescription drug packages be an sNDC, consisting of the NDC plus a unique 8-digit numerical serial number. Given the FDA recommendation for SNI, please comment on the necessity of having the serial number allow for alpha-numeric possibilities and under what standards this might be achieved.

3. Blood and blood components currently use either the ISBT 128 standard or Codabar for product package identification. In addition, hematopoietic stem cells derived from peripheral and cord blood use the ISBT 128 standard for product package identification. Please comment on whether these standards should be designated as the SNI for such products.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments 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.

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 only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.regulations.gov*.

Dated: January 8, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–833 Filed 1–15–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0659]

Draft Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated January 2009. The draft guidance document provides establishments that manufacture HCT/Ps with recommendations for complying with CGTP requirements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 16, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated January 2009. This guidance provides establishments that manufacture HCT/Ps with recommendations for complying with CGTP requirements under part 1271 (21 CFR Part 1271), subpart D (Current Good Tissue Practice), and requirements under part 1271, subpart E (Additional Requirements for Establishments Described in § 1271.10). This guidance also addresses whether the establishment registration and HCT/P listing requirements under part 1271, subparts A and B apply in certain instances.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft 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 in part 1271, subparts D and E, and §§ 1271.10 and 1271.21 have been approved under OMB Control No. 0910–0543.