welcome comment on any aspect of the draft guidance.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 We believe that the serialized National Drug Code (sNDC) described in the draft guidance is appropriate for package level identification for most prescription drugs; however, it might not be useful at the pallet or other intermediate level, such as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 FDA's draft guidance recommends that the SNI for most prescription drug packages be an sNDC, consisting of the NDC plus a unique 8-digit numerical serial number.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.

III. Commentsuidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding the draft guidance. 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 the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination 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*.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: January 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–919 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–0510]

Draft Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories; 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: Submission of Laboratory Packages by Accredited Laboratories.'' The draft guidance document provides information and recommendations about accreditation standards for laboratories and the quality and type of data that accredited laboratories produce to support testing results submitted to FDA about the admissibility of detained articles offered for import. We are taking this action under a recommendation made by the President's Interagency Working Group on Import Safety (Working Group).

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 Executive Operations (HFC–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests.

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: Donna Porter, Division of Field Science (HFA–141), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7605.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Submission of Laboratory Packages by Accredited Laboratories.'' The draft guidance is about accreditation standards for laboratories and about the quality and type of data that accredited laboratories should produce in support of testing results submitted to FDA pertaining to the admissibility of detained articles offered for import of all product types (i.e., biological products, drugs, devices, and food) that we regulate. FDA is taking this action under a recommendation made by the President's Interagency Working Group on Import Safety (Working Group). The Working Group was to conduct a comprehensive review of the U.S. import system and identify ways to further increase the safety of imports entering the country, and it presented its initial findings to the President on September 10, 2007, in a report entitled ''Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety.''

On November 6, 2007, the Working Group presented to the President its Import Safety Action Plan (Action Plan), which contains short- and long-term recommendations for continuing to improve the safety of imports entering the United States. The Action Plan recommended that FDA issue guidance that ''would set standards for the sampling and testing of imported products, including the use of accredited laboratories submitting data to FDA to assist in evaluating whether an appearance of a violation may be resolved.''

The issuance of the draft guidance is, therefore, consistent with the Action Plan and also 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 requirements of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. 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. A copy of the draft guidance and received comments are available for public examination 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 draft guidance at either *http://www.fda.gov/ora* or *http://www.regulations.gov*.