entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: 5 U.S.C. App. 2, section 10(a).

Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: January 9, 2009.

Barry M. Straube,

Chief Medical Officer and Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. E9–943 Filed 1–15–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Mission, Organization, Functions, and Delegations of Authority

This notice amends Part K of the Statement of Mission, Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), as follows: Chapter KE, Administration for Native Americans (ANA), as last amended in 60 FR 17084–85, 04/04/95. This notice establishes the Division of Policy, Planning and Evaluation and moves the support staff function to the Office of the Commissioner. The changes are as follows:

I. Chapter KE. Administration for Native Americans

A. Delete KE. 00 Mission in its entirety and replace with the following:

KE. 00 Mission. The mission of the Administration for Native Americans is to promote the goal of self-sufficiency and cultural preservation for Native Americans by providing social and economic development opportunities through financial assistance, training, and technical assistance to eligible Tribes and Native American communities, including American Indians, Alaska Natives, Native Hawaiians, and other Native Pacific Islander organizations. ANA provides funding for community-based projects that are designed to improve the lives of Native children and families and reduce long-term dependency on public assistance. Competitive funding authorized under the Native American Programs Act of 1974, as amended, for community-based projects is provided through three competitive discretionary grant programs to eligible Tribes and non-profit Native American organizations: Social and economic development, language preservation, and environmental regulatory enhancement.

B. Delete KE. 10 Organization in its entirety and replace with the following:

KE.10 Organization. The Administration for Native Americans is headed by a Commissioner who is confirmed by the Senate and reports directly to the Assistant Secretary for Children and Families.

The ANA organization includes the: Office of the Commissioner (KEA); Intra-Departmental Council on Native American Affairs (KEB); Division of Program Operations (KEC); Division of Policy, Planning and Evaluation (KED).

C. Delete KE.20 Functions in its entirety and replace with the following:

KE. 20 Functions

A. The Office of the Commissioner provides executive leadership and management strategies for all components of ANA. As required by statute, the Commissioner is Chair of the Intra-Departmental Council on Native American Affairs and advises the Secretary on all matters affecting Native Americans that involve the Department. The Commissioner serves as an effective and visible advocate on behalf of Native Americans within the Department, and with other departments and agencies of the Federal Government regarding all Federal policies affecting Native Americans. The Commissioner provides policy direction and guidance to ACF Regional Offices with respect to programs for Urban Indians, off-Reservation Indians, and other Native American projects in Hawaii and the Pacific Islands. The Commissioner oversees the Native Hawaiian Revolving Loan Fund administered by the Office of Hawaiian Affairs. In the absence of the Commissioner, the Deputy Commissioner is responsible for all organizational management.

The Management Operations Staff (MOS) is responsible for ANA Budget and Administrative functions. MOS coordinates ANA budget activities, the ANA funding decision memo, data collection, personnel actions, ANA's electronic library, tracking of required grant reports, and oversees contract expenditures. The staff members control the flow of correspondence, including receipt of and response to Freedom of Information Act requests.

B. The Commissioner is the Chair of the Intra-Departmental Council on Native American Affairs (ICNAA) and advises the Secretary on Native American issues. ICNAA staff members provide support to the Commissioner. ICNAA develops and promotes HHS policy to provide greater access and quality services for American Indians, Alaska Natives, and Native Americans (AI/AN/NAs) throughout the Department and where possible, the Federal Government; promotes implementation of HHS policy and agency plans on consultation with AI/AN/NAs and Tribal Governments; identifies and develops legislative, administrative, and regulatory proposals that promotes an effective, meaningful AI/AN/NA policy to improve health and human services for AI/AN/NAs; identifies and develops comprehensive Departmental strategy proposal to promote self-sufficiency and self-determination for all AI/AN/NA people; and promotes the Tribal/Federal government-to-government relationship on a Department-wide basis in accordance with Presidential Executive Order.

C. The Division of Program Operations (DPO) is responsible for the administration of discretionary grant programs to eligible Tribes and non-profit Native American organizations. The responsibilities include (1) Annual grant competitions and coordination of the panel review process, (2) development of ANA's Program Announcements, (3) grant oversight, and (4) grant close-out procedures. The DPO also manages and coordinates activities that support the ACF Native American Affairs Workgroup.

D. The Division of Policy, Planning and Evaluation (DPPE) is responsible for development of organizational policies and planning; community impact evaluation; management of quarterly grantee project assessment; oversight of training and technical contracts; coordination of training and technical assistance activities in Alaska, the Pacific Basin, and the lower forty-eight states; development of organizational and Congressional reports; and completion of special organizational

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