the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards-related documents. After publication in the **Federal Register**, this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 029'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/MedicalDevices.*

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm*

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) either electronic or written comments regarding this document. It is no longer necessary to send two copies of mailed comments. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 029. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: August 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20323 Filed 8–17–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0840]

Hospira, Inc.; Withdrawal of Approval of a New Drug Application for DEXTRAN 70

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for DEXTRAN 70 (6% Dextran 70 and 0.9% NaCl or/5% Dextrose 500 mL Glass Bottle) held by Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045. Hospira, Inc., has notified the Agency in writing that this product is no longer marketed and has requested that approval of the application be withdrawn.

DATES: Effective August 20, 2012.

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

SUPPLEMENTARY INFORMATION: Hospira, Inc., has requested that FDA withdraw approval of NDA 080–819, DEXTRAN 70 (6% Dextran 70 and 0.9% NaCl or/5% Dextrose 500 mL Glass Bottle) under the process in § 314.150(c)(21 CFR 314.150(c)), stating that the product is no longer marketed. By its own request, Hospira, Inc., has also waived its opportunity for a hearing provided under § 314.150(a).

Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Biologics Evaluation and Research, by the Commissioner of Food and Drugs, approval of NDA 080–819, DEXTRAN 70 [6% Dextran 70 and 0.9% NaCl or/5% Dextrose 500 mL Glass Bottle], and all amendments and supplements thereto, is hereby withdrawn, effective August 20, 2012. Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: August 9, 2012.

Karen Midthun,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 2012–20280 Filed 8–17–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes National Indian Health Outreach and Education Program Funding Opportunity

Announcement Type: New Limited Competition.

Funding Announcement Number: HHS–2012–IHS–NIHOE–0003.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: September 10, 2012.

Review Date: September 12, 2012.

Earliest Anticipated Start Date: September 30, 2012.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications for the Office of Direct Service and Contracting Tribes on the National Indian Health Outreach and Education (NIHOE–III) program funding opportunity that includes outreach and education activities on the following: The Patient Protection and Affordable Care Act, Public Law 111–148 (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, collectively known as the Affordable Care Act (ACA) and the Indian Health Care Improvement Act (IHCIA), as amended. This national outreach and educational program is authorized under the Snyder Act, codified at 25 U.S.C. 13, and the Transfer Act, codified at 42 U.S.C. 2001(a). This program is described in the Catalog of Federal Domestic Assistance under CFDA number 93.933.

Background

The NIHOE–III programs carry out health program objectives in the American Indian/Alaska Native (AI/AN) community in the interest of improving Indian health care for all 566 Federally-recognized Tribes including Tribal governments operating their own health care delivery systems through self-determination contracts and compacts