Dated: March 26, 1997.

Gary N. Kimble,

Commissioner, Administration for Native Americans.

[FR Doc. 97–8729 Filed 4–4–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. 93612–971]

Administration for Native Americans: Availability of Financial Assistance

ACTION: Announcement of availability of competitive financial assistance for projects in competitive areas administered by the Administration for Native Americans for American Indians, Native Hawaiian, Alaska Natives and Native American Pacific Islanders; Correction

In notice document 93612–971 beginning on page 44122 in the issue of Tuesday, August 27, 1996, make the following corrections:

1. On pages 44124, 44129, 44127, and 44132 in section D titled Eligible Applicants, the following sentence repeated on each of those pages, ''An organization can conclusively establish that it meets this requirement through a signed statement or resolution stating that its duly elected or appointed board of directors are either Native Americans or Native Alaskans or a copy of the organizational charter or by-laws that clearly states that the organization has a board drawn from members of these groups'' should read, ''To establish compliance with the requirement in the regulations for a Board representative of the community applicants should provide information establishing that at least ninety (90) percent of the individuals serving on a non-profit applicant's board fall into one or more of the following categories: (1) A current or past member of the community to be served; (2) a prospective participant or beneficiary of the project to be funded; or (3) have a cultural relationship with the community to be served.''

Dated: March 26, 1997.

Gary N. Kimble,

Commissioner, Administration for Native Americans.

[FR Doc. 97–8733 Filed 4–4–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0124]

COOK OB/GYN®; Humanitarian Device Exemption Approval of Harrison Fetal Bladder Stent Set (Lowery Modification)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the humanitarian device exemption (HDE) application by COOK OB/GYN®, Spencer, IN, under the Federal Food, Drug, and Cosmetic Act (the act) of the Harrison Fetal Bladder Stent Set (Lowery Modification).

DATES: Petitions for administrative review by May 7, 1997.

ADDRESSES: Written requests for copies of the summary of safety and probable benefit and petitions for administrative review should be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Donna-Bea Tillman, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION: On November 13, 1996, COOK OB/GYN®, Spencer, IN 47460, submitted to CDRH an application for an HDE for the Harrison Fetal Bladder Stent Set (Lowery Modification). The device is a fetal bladder stent and is indicated for fetal urinary tract decompression following the diagnosis of fetal postvesicular obstructive uropathy in fetuses 18 to 32 weeks gestational age.

In accordance with 21 CFR 814.116(a), this HDE was not referred to the Obstetrics and Gynecology Devices Panel, an FDA advisory committee, for review and recommendation because the information in the HDE substantially duplicates information previously reviewed by this panel.

On February 14, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and probable benefit upon which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from the office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515 (d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue(s) to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before May 7, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitioners may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 520(h) of the act (21 U.S.C. 360j(h)), 21 CFR 814.116(b), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: February 20, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–8707 Filed 4–4–97; 8:45 am]

BILLING CODE 4160–01–F