ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0566. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine (OMB Control Number 0910–0566)—Extension

CVM's (Center for Veterinary Medicine) ''Guidance for Industry #79—Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine'' describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training or experience to be understood and resolved. Further, the guidance details information on how the agency intends to interpret and apply provisions of the existing regulations regarding internal agency review of decisions. In addition, the guidance outlines the established recommended procedures for persons who are applicants, including sponsor applicants or manufacturers, for animal drugs or other products regulated by CVM, that wish to submit a request for review of a scientific dispute. When an applicant has a scientific disagreement and a written decision by CVM, the applicant may submit a request for review of that decision by following the established agency channels of supervision for review.

Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

In the **Federal Register** of March 26, 2008 (73 FR 16021), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
10.75	2	4	8	10	80

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimated annual reporting burden is based on CVM's experience over the past 3 years in handling formal appeals for scientific disputes. The number of respondents multiplied by the annual frequency of response equals the total annual responses. The number of hours per response is based on discussions with industry and may vary depending on the complexity of the issue(s) involved and the duration of the appeal process.

Dated: June 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14515 Filed 6–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 18, 2008, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Louise E. Magruder, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–1248, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512515. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss and make recommendations on issues relevant to the potential for automated differential cell counters being waived under the Clinical Laboratory Improvement Amendments of 1988. The discussion will include pre-analytical, analytical, and post-analytical issues associated with performing automated hematology complete blood counts and differentials in a waived setting. (See *www.fda.gov/cdrh/oivd/guidance/1171.html*).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact

person on or before July 9, 2008. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:15 a.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 1, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 8, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 240–276–8932, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 20, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–14495 Filed 6–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Clinical and Preventive Services, Division of Nursing Services Nursing Program, Schools of Nursing

Announcement Type: Competitive Continuation and New Grants.

Funding Announcement Number: HHS–2008–IHS–NU–0001.

Catalog of Federal Domestic Assistance Numbers(s): 93.970

Key Dates:

Application Deadline Date: August 8, 2008.

Review Date: August 18, 2008.

Award Status Notification: August 22, 2008.

Earliest Anticipated Start Date: September 1, 2008.

I. Funding Opportunity Description

The Indian Health Service (IHS), Office of Clinical and Preventive Services, Division of Nursing Services, announces a competitive grant application for existing and new grantees under the Nursing Education Program for American Indians/Alaska Natives (AI/AN5). This program is authorized under section 112 of the Indian Health Care Improvement Act, Public Law 94–437 as amended. This program is described at 93.970 in the Catalog of Federal Domestic Assistance (CFDA).

The purpose of the Nursing Program Schools of Nursing is to increase the number of nurses, nurse midwives, nurse anesthetists, and nurse practitioners who deliver health care services to AI/ANs. The primary objectives of this grant award are to (1) recruit and train AI/AN individuals to be nurses (Graduate and Undergraduate), (2) provide scholarships to AI/AN individuals enrolled in schools of nursing to pay tuition, books, fees, and stipends for living expenses; (3) provide a program that encourages AI/AN nurses (Graduate and Undergraduate), to provide or continue to provide, health care services in AI/AN health care programs, and (4) provide a program that increases the skills of, and provides continuing education to AI/AN nurses (Graduate and Undergraduate). Each proposal must respond to all of the above four objectives.

The awards will be based on the following:

At least one project to a public or private college or university school of nursing, which provides for a Master of Science in Nursing (MSN), Doctorate in Nursing Practice (DNIP), or Bachelor of Science in Nursing (BSN), degree in nurse midwifery, nurse practitioner, nurse anesthesia, or nursing-healthcare administration, not to exceed $350,000 per year up to a project period of five years.

At least one project to a public, private, college or university program of nursing, which provides for an Associate Degree in Nursing (ADN), not to exceed $335,000 per year up to a project period of five years.

At least one project to a Tribally controlled community college or university that has a formal bridge program agreement to a college or university at which AI/AN students can complete an ADN, BSN, or MSN/DNP degree, not to exceed $300,000 per year up to a project period of five years.

II. Award Information

Type of Awards: Grants.

Estimated Funds Available: The total amount identified for fiscal year (FY) 2008 is $1,335,000. The awards are for 60 months in duration and the average award is approximately $337,000. Each program type will receive different amounts of funding based on the level of nursing degree. Continuation awards are subject to the availability of funds and satisfactory performance.

Anticipated Number of Awards: Four awards will be issued under the announcement to existing or new award recipients on a competitive base.

Project Period: Five Years.

Award Amount: The following will be awarded according to the nursing program level per year:

- $350,000 to one school at the MSN or DNP level,
- $350,000 to at least one school at the BSN level,
- $335,000 to at least one school at the ADN level, and
- $300,000 to a Tribally controlled college/university with a bridge to an ADN/BSN/MSN/DNP level.

III. Eligibility Information

1. The following organizations are eligible:

A. Public or private schools of nursing.

B. Tribally controlled community college nursing programs and Tribally controlled post-secondary vocational institutions (as defined in 20 U.S.C. 2397h(2)).

C. All organizations providing for the ADN, BSN, MSN or DNP to AI/AN students.

While Indian health programs have need for advance practice nurses who are nurse midwives and nurse practitioners, its greatest need in the field of advance practice nursing is nurse anesthesia, in addition to nurse administrators trained at the graduate level and clinical nurses at the bachelor's level. Therefore, preference will be given to applicants who have programs:

A. That provide a preference to Indians,

B. That train nurse anesthetists, nurse midwives, nurse practitioners, and BSN nurses,

C. Whose curriculum is taught in an interdisciplinary manner with other health professional students such as