there was a red tide and then examined the data to see if red tide exposure had an effect on symptom reports or PFT results.

NCEH requests a revision of data collection procedures for the currently approved project and an additional three year extension. Unfortunately, the exposures experienced by the study cohort have been minimal, and NCEH plans to conduct another study (using the same symptom surveys and PFTs) during a more severe red tide event. First, NCEH wants to quantify the levels of cytokines in nasal exudates to assess whether they can be used to verify exposure and to demonstrate a biological effect (i.e., allergic response) following inhalation of aerosolized brevetoxins. NCEH will collect nasal exudates at the same time the PFTs are done.

NCEH plans to include the study subjects who have been involved in the earlier studies and any new individuals (n=25) who have been hired to work at the relevant beaches.

There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Instrument type	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pulmonary History Survey	10	1	20/60	3
Symptom survey	25	6	5/60	13
Total				16

Catina Conner,

Assistant Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–20913 Filed 9–9–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Ethics Subcommittee, Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC); Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention announce the following Subcommittee meeting.

Name: Ethics Subcommittee, Advisory Committee to the Director.

Time and Date: 12 p.m.–1:30 p.m., EDT, Thursday, September 25, 2008.

Place: This meeting will be held by conference call. The call in number is (866) 919–3560 and entering code 4168828.

Status: Open to the public. The public is welcome to comment during the public comment period which is tentatively scheduled from 1 p.m.–1:15 p.m.

Purpose: The Ethics Subcommittee will provide counsel to the ACD, CDC regarding a broad range of public health ethics questions and issues arising from programs, scientists and practitioners.

Matters To Be Discussed: Agenda items will include review of ethics guidance for public health emergency preparedness and response.

For Further Information Contact: For more information about this meeting contact Drue Barrett, PhD., Designated Federal Official, Ethics Subcommittee, CDC, 1600 Clifton Road, NE., M/S D–50, Atlanta, Georgia 30333, Telephone (404)639–4690, *e-mail: dbarrett@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 4, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–20967 Filed 9–9–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0239]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 10, 2008.

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 0910–0409. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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.

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring (OMB Control Number 0910–0409)—Extension

FDA is requesting OMB approval of the information collection requirements contained in 21 CFR 315.4, 315.5, and 315.6. These regulations require manufacturers of diagnostic radiopharmaceuticals to submit information that demonstrates the safety and effectiveness of a new diagnostic radiopharmaceutical or of a new indication for use of an approved diagnostic radiopharmaceutical.

In response to the requirements of section 122 of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), FDA published a final rule in the **Federal**

Register of May 17, 1999 (64 FR 26657) amending its regulations by adding provisions that clarify the agency's evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis or monitoring of diseases. The regulation describes the kinds of indications of diagnostic radiopharmaceuticals and some of the criteria that the agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262). Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables FDA to properly evaluate the safety and effectiveness profiles of a new diagnostic radiopharmaceutical or a new indication for use of an approved diagnostic radiopharmaceutical.

The rule clarifies existing FDA requirements for approval and evaluation of drug and biological products already in place under the authorities of the act and the PHS Act. The information, which is usually submitted as part of a new drug application or biologics license application or as a supplement to an approved application, typically includes, but is not limited to, nonclinical and clinical data on the pharmacology, toxicology, adverse events, radiation safety assessments, and chemistry, manufacturing, and controls. The content and format of an application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50). Under 21 CFR part 315, information required under the act and needed by FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals still needs to be reported.

Based on the number of submissions (that is, human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals) that FDA receives, the agency estimates that it will receive approximately two submissions annually from two applicants. The hours per response refers to the estimated number of hours that an applicant would spend preparing the information required by the regulations. Based on FDA's experience, the agency estimates the time needed to prepare a complete application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulation does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (collection of information approved by OMB under OMB control number 0910–0001). In fact, clarification in these regulations of FDA's standards for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well established, low risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies. Table 1 of this document contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by existing regulations. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

In the **Federal Register** of April 28, 2008 (73 FR 22955), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

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
315.4, 315.5, and 315.6	2	1	2	2,000	4,000
Total					

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

Dated: August 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20933 Filed 9–9–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Statutorily Mandated Single Source Award; Quentin N. Burdick American Indians Into Nursing Program

AGENCY: Indian Health Service, HHS.

ACTION: Notice of intent to fund a statutorily mandated single source grant award to the University of North Dakota, Quentin N. Burdick American Indians into Nursing Program, also known as the Recruit American Indians Into Nursing (RAIN) Program.

Project Period: August 1, 2008–July 31, 2013.

Amount of Award: $350,000.

Authority: This program is authorized under 25 U.S.C. 1616e(e) as amended, and requires the IETS to provide one grant to establish and maintain a program at the University of North Dakota (UND) to be known as the ''Quentin N. Burdick American Indians into Nursing Program.''

Single Source Justification: The single source award is statutorily mandated under 25 U.S.C. 1616e(e), as amended and shall to the maximum extent feasible, coordinate with the Quentin N. Burdick Indians Into Psychology Program.

Description of the Project: 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. Additional high-need areas are nurse administrators trained at the graduate level and clinical nurses at the bachelor's level. Therefore, UND will maintain or incorporate the following:

A. Provide a preference to Indians,

B. Train nurse anesthetists, nurse midwives, nurse practitioners, nurse administrators and Bachelor's of Science in Nursing (BSN) nurses,

C. Teach curriculum in an interdisciplinary manner with other