OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0632. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Form FDA 3728, Animal Generic Drug User Fee Act Cover Sheet—21 U.S.C. 379j–21 (OMB Control Number 0910–0632)—Extension

Section 741 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379j–21) establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs, (2) annual fees for certain generic new animal drug products, and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j–21(a)). Because the submission of user fees concurrent with applications is required, the review of an application cannot begin until the fee is submitted. Form FDA 3728 is the Animal Generic Drug User Fee Act (AGDUFA) Cover Sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees.

In the **Federal Register** of October 5, 2011 (76 FR 61709), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Form Number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3728	20	2	40	.08 (5 min.)	3.2

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

Respondents to this collection of information are generic animal drug applicants. Based on FDA's database system, there are an estimated 20 sponsors of new animal drugs potentially subject to AGDUFA.

Dated: July 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–17369 Filed 7–16–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Use of Influenza Disease Models To Quantitatively Evaluate the Benefits and Risks of Vaccines: A Technical Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: ''Use of Influenza Disease Models to Quantitatively Evaluate the Benefits and Risks of Vaccines: A Technical Workshop.'' The purpose of this public workshop is to provide stakeholders a forum to discuss the design of a model to quantitatively estimate the benefits and risks of a hypothetical influenza vaccine, and to seek from a range of experts, feedback on the current version of the model used by the Center for Biologics Evaluation and Research (CBER) and suggestions for further development.

The public workshop will include presentations and panel discussions with experts from academia, regulated industry, government, and other stakeholders.

Date and Time: The public workshop will be held on August 23, 2012, from 9 a.m. to 4 p.m.

Location: The public workshop will be held at the Bethesda North Marriott Hotel & Conference Center; 5701 Marinelli Rd., Bethesda, MD 20852; 301–822–9200.

Contact Person: Richard Forshee, Center for Biologics Evaluation and Research (HFM–210), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6042, email: *Richard.Forshee@fda.hhs.gov.*

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone, and fax numbers, and email address) to Richard Forshee (see *Contact Person*) by August 16, 2012. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space-available basis beginning at 8 a.m. If you need special accommodations due to a disability, please contact Richard Forshee (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshop will provide an opportunity for discussions on the application of open source influenza infectious disease computer simulation models to generate quantitative estimates of the benefits and risks of influenza vaccination.

The public workshop presentations and panel discussions will: (1) Discuss recent developments in open-source, agent-based, publicly available computer simulation tools to model influenza and other infectious diseases; (2) discuss and seek technical feedback on the CBER quantitative model of influenza vaccine benefit/risk; and (3) discuss possible applications of quantitative benefit/risk assessment methods to vaccine assessment of quantitative benefit/risk assessment methods to vaccine assessment.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.* Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: July 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–17337 Filed 7–16–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Nursing, Public Health Nursing Community Based Model of PHN Case Management Services

Announcement Type: New.

Funding Announcement Number: HHS–2012–IHS–PHN–0001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: August 14, 2012.

Review Date: August 20, 2012.

Earliest Anticipated Start Date: September 1, 2012.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications for the Office of Clinical and Preventive Services (OCPS), Community Based Model of Public Health Nursing Case Management Services. This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2011; the Public Health Service Act, as amended, 42 U.S.C. 241; and the Indian Health Care Improvement Act, as amended, (IHCIA), 25 U.S.C. 1653(c). This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The IHS OCPS Public Health Nursing (PHN) Program serves as the primary source for national advocacy, policy development, budget development, and allocation for clinical, preventive, and public health nursing programs for the IHS Area Offices and Service Units. The IHS PHN Program is a community health nursing program that focuses on the goals of promoting health and quality of life, and preventing disease and disability. The PHN program provides quality, culturally sensitive health promotion and disease prevention nursing services through primary, secondary and tertiary prevention services to individuals, families, and community groups. It provides leadership in articulating the clinical, preventive, and public health needs of American Indian/Alaska Native (AI/AN) communities and developing, managing, and administering program functions related to PHN.

Purpose

The purpose of this IHS cooperative agreement is to improve specific health outcomes of an identified high risk group of patients through a community case management model that utilizes the PHN as a case manager. Research indicates nursing case management is a cost effective way to maximize health outcomes. Case management involves the client, family, and other members of the health care team. Quality of care, continuity, and assurance of appropriate and timely interventions are also crucial. In addition to reducing the cost of health care, case management has proven its worth in terms of improving rehabilitation, improving quality of life, increasing client satisfaction and compliance by promoting client self-determination. The PHN model of community based case management utilizes roles and functions of PHN services of assessment, planning, coordinating services, communication and monitoring. The goals and outcomes of the PHN case management model are early detection, diagnosis, treatment and evaluation that will improve health outcomes in a cost effective manner. This model utilizes all prevention components of primary, secondary and tertiary prevention in the home with patient and family. The community based case management model addresses the PHN scope of practice of working with individuals and families in a population-based practice to provide primary nursing care services. This project will focus on a PHN community based case management model. The project will be conducted in a phased approach, using the nursing process—assessment, planning, implementation, and evaluation.

First Phase: Assessment—Complete a generic community assessment (most PHN programs have this readily available as a part of their annual program plans). Include, if available, pertinent data from other local community assessments and local health status data of the community in the assessment. In addition, obtain input from key stake-holders such as community members, Tribal leaders, healthcare administration and community health groups to determine the health care priorities. Obtain approval for the establishment of the PHN case management program from healthcare administration, governing boards and medical executive committees as needed.

Second Phase: Planning—Based on the community assessment, the high risk population is identified and the planning of the case management project begins. Develop case management services addressing the priority health issues identified from the community assessment. Plan specific guidelines for the case management services of the high risk group of patients such as admission criteria, caseload size, policies and procedures, and an evaluation plan to include data tracking for outcomes generated. Identify if there is a best practice case management model available to replicate to target the identified high risk population. Obtain additional staff training needed for the community based nurse case management model such as evidence based practice, motivational interviewing, nurse competencies and any other training that would be applicable to the health issues identified in the case management model. Identify or develop patient education materials and community education materials for the program. Develop plans for project sustainability.

Third Phase: Implementation—The case management program includes admission criteria of the high risk population, caseload size, and appropriate health care standards. Establish patient caseload. Monitor progress and make adjustments as needed. Track patient data outcomes. Continue to plan ongoing sustainability of the program after the award period ends.

Fourth Phase: Patient Satisfaction—In order to evaluate program services; initiate a patient satisfaction program, such as one that provides patients with an opportunity to provide feedback on their experiences to assess the satisfaction of the population served. Analyze findings so a concentrated effort is made to relate the customer satisfaction results to internal process metrics, and examine trends over time in order to take action on a timely basis. Evaluate and revise the case management program if needed, review policies and procedures, education materials and staff competencies semi-annually. To the extent permitted by law, report back to key stake-holders progress of the project, especially to inform clients about changes brought about as a direct result of listening to their needs. Each site will share program material with IHS Headquarters PHN program. This information will be shared IHS-wide for replication of the project across IHS with credit given to