study requirement. Approximately half of the average submitted PMAs (32) require associated postapproval studies (i.e., followup of patients used in clinical trials to support the PMA or additional preclinical information) that is labor-intensive to compile and complete, and the other PMAs require minimal information. Based on experience and consultation with industry, FDA has estimated that preparation of reports and information required by this section require 6,075 hours (135 hours per respondent).

• § 814.84—*Reports*: 450 burden hours

Postapproval requirements described in § 814.82 require a periodic report. FDA has determined respondents meeting the criteria of § 814.84 will submit reports on a periodic basis. As stated previously, the range of PMAs fitting this category averaged approximately 45 per year. These reports have minimal information requirements. FDA estimates that respondents will construct their report and meet their requirements in approximately 10 hours. This estimate is based on FDA's experience and on consultation with industry. FDA estimates that the periodic reporting required by this section will take 450 hours.

Statutory Burden: The total hours for statutory burden is 1,750. This burden estimate was based on actual real FDA data tracked from January 1, 1998, to the present, and an estimate was derived to forecast future expectations with regard to this statutory data.

Recordkeeping

The recordkeeping burden in this section involves the maintenance of records used to trace patients and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records would be required only of those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMAs are eventually approved and 75 percent of those have original clinical trial data. Therefore, approximately 45 PMAs a year (64 annual submissions times 70 percent) would be subject to these requirements. Also, because the requirements apply to all active PMAs, all holders of active PMA applications must maintain these records. PMAs have been required since 1976, and there are 1,075 active PMAs that could be subject to these requirements, based on actual FDA data. Each study has approximately 200 subjects, and at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 17 hours. The aggregate burden for all 1,075 holders of approved original PMAs, therefore, is 18,275 hours (1,075 approved PMAs with clinical data x 17 hours per PMA).

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions to approval to ensure the device's continuing safety and effectiveness.

Dated: March 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–7607 Filed 4–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0268]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Biological Products: Reporting of Biological Product Deviations in Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Biological Products: Reporting of Biological Product Deviations in Manufacturing'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 31, 2003 (68 FR 75572), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0458. The approval expires on March 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: March 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–7608 Filed 4–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health; Office of the Director

Notice of Meeting

The Office of the Director, National Institutes of Health (NIH), announces a meeting of the NIH Blue Ribbon Panel on Conflict of Interest Policies, a working group of the Advisory Committee to the Director, NIH. The meeting is scheduled for April 5–6, 2004, beginning at 8:30 a.m. each day.

The meeting will be held at the NIH, 9000 Rockville Pike, Bethesda, Maryland, Building 31C, Conference Room 6. Attendance will be limited to space available. In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

On April 5, the Panel will be in public session from 10 a.m.–2 p.m.; the Panel will meet in closed, Executive Session, from 8:30–10 a.m. and from 2:15 p.m.–4 p.m. On April 6, the Panel will meet in closed, Executive Session, from 8:30 a.m.–2 p.m. Closed sessions will be used for the Panel to work on their recommendations and the report. The agenda will be posted on the NIH Web site (*http://www.nih.gov*) prior to the meeting. Any person wishing to make a presentation should notify Charlene French, Office of Science Policy, National Institutes of Health, Building 1, Room 103, Bethesda, Maryland 20892, telephone 301–496–2122 by April 2, 2004, or by e-mail: *blueribbonpanel@mail.nih.gov*.

Oral comments will be limited to 5 minutes. Due to time constraints, only one representative from each organization will be allotted time for oral testimony. The number of speakers and the time allotment may also be limited by the number of presentations.

The opportunity to speak will be based on a first come first served basis. All requests to present oral comments should include the name, address, telephone number, and business or professional affiliation of the interested party, and should indicate the areas of interest or issue to be addressed. Please provide, if possible, an electronic copy of your comments.

Any person attending the meeting who has not registered to speak in advance of the meeting will be allowed to make a brief oral statement during the time set aside for public comment, if time permits and at the discretion of the co-chairs.

Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Charlene French at the address listed earlier in this notice in advance of the meeting.

Dated: March 30, 2004.

LaVerne Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–7696 Filed 4–1–04; 11:04 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Refugee Resettlement; Wilson/Fish Discretionary Grant Program

Funding Opportunity Title: Wilson/Fish Discretionary Grant Program.

Announcement Type: Standing.

Funding Opportunity Number: HHS–2004–ACF–ORR–RW–0005.

Category of Funding Activity: ISS Income Security and Social Services.

CFDA Number: 93.583.

Due Dates for Applications: This is a standing announcement applicable from the date of publication until canceled or modified by the Director of the Office of Refugee Resettlement. The closing date for new projects is January 31 of each year. The closing date for existing projects that are applying to begin a new project period is April 30 of each year. Under Category One, if a State withdraws from the program, the Director may invite applications outside of the proposed closing date, if necessary, to respond to the needs of the State's refugee population.

I. Funding Opportunity Description

Executive Summary: The Office of Refugee Resettlement (ORR) announces that applications will be accepted from public and private non-profit organizations, including faith-based and community organizations, under a standing announcement for Wilson/Fish projects which propose alternative approaches to serving refugees.[1] The purpose of Wilson/Fish projects is to provide integrated services and cash assistance to refugees in order to increase refugees' prospects for early employment and self-sufficiency, reduce their level of welfare dependence and promote coordination among voluntary resettlement agencies and service providers. Projects will be accepted under either of two categories: (1) Projects to establish or maintain a refugee program in a State where the State is not participating in the refugee program or is withdrawing from the refugee program or a portion of the program; and (2) projects to provide an alternative to the existing system of assistance and services to refugees. Funding is available to these projects under the "Wilson/Fish'' authority. This notice replaces the notice published in the **Federal Register** of April 22, 1999 (64 FR 19793).

The Office of Refugee Resettlement (ORR) announces that applications will be accepted from public and private non-profit organizations including faith-based and community organizations, under this standing announcement for Wilson/Fish projects which propose alternative approaches to serving refugees. Projects will be accepted under either of two categories: (1) Projects to establish or maintain a refugee program in a State where the State is not participating in the refugee program or is withdrawing from the refugee program or a portion of the program; and (2) projects to provide an alternative to the existing system of assistance and services to refugees.

Category One of this announcement provides an opportunity for an applicant(s) to continue the provision of refugee program services and assistance, including refugee cash and medical assistance, employment and other social services and targeted assistance in a State when the State elects to discontinue participation in the program or is not currently participating in the program. This category may also be used when a State elects to cease participation in all of the above components except for medical assistance and preventive health and where the Director of ORR believes that continued resettlement of refugees in that State is in the best interests of the government. A consortium of voluntary agencies, a lead voluntary agency, or another public or private non-profit agency may apply to administer and provide services and assistance to refugees in the State or local geographic area.

Category Two provides interested applicants an opportunity to implement alternative projects to promote refugee self-sufficiency. Some examples include: (1) Where assistance and services for refugees receiving refugee cash assistance (RCA) and those receiving Temporary Assistance for Needy Families (TANF) could be provided in a better coordinated, effective, and efficient manner; (2) where TANF-eligible refugees may not have access to timely, culturally and linguistically compatible services or employment and training programs; (3) where the regulatory options for delivery of services and assistance to refugees do not present the most effective resettlement in that location, and where resettlement could be made more effective through the implementation of an alternative project; (4) where refugees, particularly in two-parent families, are in danger of becoming dependent upon welfare and using the full-time period of assistance allowed under the TANF program in a State, thereby removing the ability of the family to access TANF as a safety net in the future; (5) where the continuity of services from the time of arrival until the attainment of self-sufficiency needs to be strengthened; or (6) where it is in the best interest of refugees to receive assistance and services outside the traditional welfare system.

At a minimum, applicants are expected to propose a range of services and financial assistance generally comparable to those currently available to eligible refugees in the State. Applicants in Category One may propose to transfer and serve in the Wilson/Fish project those clients who have not completed their period of eligibility under the existing RCA program. Applicants in Category Two

[1] Eligibility for Wilson-Fish includes refugees, asylees, Cuban and Haitian entrants, certain Amerasians from Vietnam who are admitted to the U.S. as immigrants, certain Amerasians from Vietnam who are U.S. citizens, and victims of a severe form of trafficking who receive certification or eligibility letters from ORR. (See Part I of this notice on "Legislative Authority,'' and refer to 45 CFR 400.43 and the ORR State Letter #01–13 on the Trafficking Victims Protection Act dated May 3, 2001, located at *http://www.acf.dhhs.gov/programs/orr/policy/sl01-13.htm,* as modified by ORR State Letter #02–01 dated January 4, 2002, located at *http://www.acf.dhhs.gov/programs/orr/policy/sl02-01.htm).* The term "refugee,'' used in this notice for convenience, is intended to encompass these additional persons who are eligible to participate in refugee program services, including the Wilson-Fish program.