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]

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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]

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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.