responsible for any postapproval obligations, such as postmarketing clinical trials, additional product stability studies, complaint handling, recalls, postmarket reporting of the dissemination of advertising and promotional labeling materials as required under § 601.12(f)(4) and adverse experience reporting. We recommend that the final product manufacturer establish a procedure with the other participating manufacturer(s) to obtain information in these areas.

Description of Respondents: The recordkeeping and reporting recommendations described in this document affect the participating licensed manufacturer(s), final product manufacturer(s), and contract manufacturer(s) associated with cooperative manufacturing arrangements.

Burden Estimate: We believe that the information collection provisions in the draft guidance do not create a new burden for respondents. We believe the reporting and recordkeeping provisions are part of usual and customary business practice. Licensed manufacturers would have contractual agreements with participating licensed manufacturers, final product manufacturers, and contract manufacturers, as applicable for the type of cooperative manufacturing arrangement, to address all these information collection provisions.

This draft guidance also refers to previously approved collections of information found in FDA regulations at parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 803, and 807 (21 CFR parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 803, and 807). The collections of information in §§ 606.121, 606.122, and 610.40 have been approved under OMB Control No. 0910–0116; § 610.2 has been approved under OMB Control No. 0910–0206; §§ 600.12(e) and 600.80 have been approved under OMB Control No. 0910–0308; §§ 601.2(a), 601.12, 610.60, 610.61, 610.62, 610.67, 660.2(c), 660.28(a) and (b), 660.35(a), (c) through (g), and (i) through (m), 660.45, and 660.55(a) and (b) have been approved under OMB Control No. 0910–0338; §§ 803.20, 803.50, and 803.53 have been approved under OMB Control No. 0910–0437; and §§ 600.14 and 606.171 have been approved under OMB Control No. 0910–0458. The current good manufacturing practice regulations for finished pharmaceuticals (part 211) have been approved under OMB Control No. 0910–0139; the establishment registration regulations (parts 207, 607, and 807) have been approved under OMB Control Nos. 0910–0045, 0910–0052, and 0910–0387; and the labeling regulations (part 201) have been approved under OMB Control Nos. 0910–0340 and 0910–0370.

Dated: July 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–14149 Filed 7–20–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management 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 Committees: Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

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

Date and Time: The meeting will be held on September 12, 2007, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD, 301–977–8900.

Contact Person: Mimi Phan, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Mimi.Phan@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533 or 3014512535. 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 clinical data for aprotinin injection (TRASYLOL, Bayer Pharmaceuticals), a product indicated for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery who are at increased risk for blood loss and blood transfusion. This discussion follows a September 27, 2006, FDA Public Health Advisory regarding a study of aprotinin injection safety (*http://www.fda.gov/cder/drug/advisory/aprotinin20060929.htm*).

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 2007 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 August 28, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 August 20, 2007. 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 August 21, 2007.

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 Mimi Phan at 301–827–7001, at least 7 days in advance of the meeting.

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

Dated: July 16, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–14151 Filed 7–20–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

National Protection and Programs Directorate, Office of Grants and Training, Assistance to Firefighters Program Office; Agency Information Collection Activities: Submission for OMB review; Comment Request on a Reinstating Collection (Application for Assistance to Firefighters Grants (AFG))

AGENCY: Department of Homeland Security, National Protection and Programs Directorate, Office of Grants and Training. Assistance to Firefighters Program Office.

ACTION: Notice; 30-day notice of information collection under review.

SUMMARY: The Department of Homeland Security (DHS), has submitted the following information collection to the Office of Management and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). The information collection was previously published in the **Federal Register** on October 24, 2006, Vol 71, Page 62273 allowing for a 60-day public comment period. No comments were received on this existing information collection. The purpose of this notice is to allow an additional 30 days for public comments. The submission describes the nature of the information collection, the categories of respondents, the estimated burden (i.e., the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments DHS will use. This collection was previously referenced as 3067–0285. The number of collection has been corrected to 1660–0054.

DATES: Comments are encouraged and will be accepted until August 22, 2007. This process is conduced in accordance with 5 CFR 1320.10.

Comments: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Nathan Lesser, Desk Officer, Department of Homeland Security/Grants and Training, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

The Office of Management and Budget is particularly interested in comments which:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by calling Nathan Lesser, Desk Officer, Department of Homeland Security Washington, DC 20528; and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

Analysis

Agency: National Protection and Programs Directorate, Office of Grants and Training, Assistance to the Firefighters Program Office, Department of Homeland Security.

Title: Staffing for Adequate Fire and Emergency Response grants program.

Title: Assistance in Firefighters Grants (AFG).

OMB Number: 1660–0054.

Frequency of Response: On occasion.

Affected Public: Fire departments; not-for-profit institutions; local or tribal government.

Number of Respondents: 25,000 applicants; 7,000 awardees.

Estimated Time per Respondent: 12 hours for application; 4 hours for administration.

FF20–10: Summary Sheet for Assurances and Certifications—1 hour.

FF20–16: Summary Sheet for Assurances and Certifications—1.7 hours.

FF16A: Assurances—Construction Program—1.7 hours.

FF16B: Financial Status Report—1.7 hours.

FF16C: Certifications Regarding Lobbying; Debarment, Suspension and Other Responsibilities—1.7 hours.

FF20–20: Budget Information—Non-Construction Programs—9.7 hours.

Estimated Total Annual Burden Hours: 28,000 hours for grantee administration.

Description: Information sought under this submission will comprise the grant application for Assistance to Firefighters Grants. This submission is necessary in order for Department of Homeland Security (DHS) to effectively implement a competitive grant program. One of the twelve eligible activities is fire prevention and safety (FP&S). Fire departments and National, State, regional and local organizations are eligible to apply for assistance under FP&S. Because of the complexities of eligibility and the various projects that are eligible under this activity, DHS has elected to have an application period for FP&S that is separate from the FIRE Grants application period. This collection is for both applications. The information collected will be used to objectively evaluate each of the 20,000 to 25,000 anticipated applicants to determine which of the applicants' proposals in each of the activities are the closest to the established program priorities. The information is necessary in order for DHS to assess the financial needs of the applicants as well as the projected benefits to be obtained from the use of the grant funds. DHS will also use the information to determine eligibility and whether the proposed use of funds meets the requirements and intent of the legislation.

For the FY 2007 program year, there will be two functional areas under FIRE Grants that the applicants can spend the grant funds: (1) Fire Operations and Firefighter Safety (which includes emergency medical activities, training, wellness and fitness programs, firefighting equipment, and personal protection equipment), and (2) Acquisition of Response Vehicles.

Dated: July 17, 2007.

Fawn Pettigrew,

Director of Operations, National Programs and Protection Directorate, Department of Homeland Security.

[FR Doc. E7–14141 Filed 7–20–07; 8:45 am]

BILLING CODE 4410–10–P