Drug	Application Number
Cipro (ciprofloxacin) for Suspension	20–780
Allegra-D (fexofenadine hydrochloride/pseudoephedrine hydrochloride) Tablets	20–786
Cardizem (diltiazem hydrochloride) for Injection	20–792
Floxin (ofloxacin) Solution	20–799
Fortovase (saquinavir) Capsules	20–828
Prograf (tacrolimus) Capsules	50–708
Prograf (tacrolimus) Capsules	50–708/S–008
Helidac (bismuth subsalicylate tablets, metronidazole tablets, and tetracycline hydrochloride capsules)	50–719
Cellcept (mycophenolate mofetil) Tablets	50–723
Amphotec (amphotericin B) Cholesteryl Sulfate for Injection	50–729
Zithromax (azithromycin) for Injection	50–733
Idamycin-PFS (idarubicin hydrochloride) Injection	50–734
Neoral (cyclosporine) Capsules	50–735
Neoral (cyclosporine) Solution	50–736
Neoral (cyclosporine) Capsules	50–737
Neoral (cyclosporine) Solution	50–738
Omnicef (cefdinar) Capsules	50–739
Ambisome (amphotericin B) Liposome for Injection	50–740
Stromectol (ivermectin) Tablets	50–742
Bactroban (mupirocin calcium) Cream	50–746
Omnicef (cefdinir) Suspension	50–749
Primsol (trimethoprim hydrochloride) Solution	74–374/S–002

As part of its review of each of the NDA's and supplements listed in this table, FDA reviewed an EA. In each instance, FDA found that the approval of the NDA or supplement will not significantly affect the human environment. In accordance with the Council on Environmental Quality regulations in 40 CFR 1501.4(e) and FDA regulations in § 25.41, FDA prepared a FONSI for each NDA and supplement. This notice announces that the EA's and FONSI's for these human drug products may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. For a fee, copies of these EA's and FONSI's may be obtained by writing the Freedom of Information Staff (address above). The request should identify by the application number the EA's and FONSI's requested. Separate requests should be submitted for each application number. Additional information regarding the submission of freedom of information requests is available on the Internet at http://www.fda.gov/opacom/backgrounders/foiahand.html.

Dated: May 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13045 Filed 5–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0486]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 11, 1997 (62 FR 65274), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910–0045. The approval expires on April 30, 2001.

Dated: May 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13044 Filed 5–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–339]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions;

(2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Provider Cost Report Reimbursement Questionnaire and Supporting Regulations in 42 CFR 405.465, 405.481, 413.20, and 413.24; *Form No.:* HCFA–339 (OMB# 0938–0301); *Use:* The Medicare Provider Cost Report Reimbursement Questionnaire must be completed by all providers to assist in preparing an acceptable cost report, to ensure proper Medicare reimbursement, and to minimize subsequent contact between the provider and its fiscal intermediary. It is designed to answer pertinent questions about key reimbursement concepts found in the cost report and to gather information necessary to support certain financial and statistical entries on the cost report. In addition, it provides an audit trail for the fiscal intermediary. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, local and tribal government; *Number of Respondents:* 30,607; *Total Annual Responses:* 30,607; *Total Annual Hours:* 1,239,584.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer:

OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: May 11, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–13158 Filed 5–15–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the Merit Review Ad Hoc Subcommittee of the National Advisory Council on Alcohol Abuse and Alcoholism.

Purpose/Agenda: To review and evaluate grant applications.

Name of Committee: Merit Review Ad Hoc Subcommittee of the National Advisory Council on Alcohol Abuse and Alcoholism.

Date of Meeting: June 3, 1998.

Time: 8:00 p.m. to adjournment.

Place of Meeting: Pooks Hill Marriott Hotel, Bethesda, MD 20814.

Contact Person: Mark Green, Ph.D., 6000 Executive Blvd, Suite 409, Bethesda, MD 20892–7003, 301–443–2860.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; National Institutes of Health)

Dated: May 12, 1998.

Anna Snouffer,

Acting Committee Management Officer, NIH.

[FR Doc. 98–13148 Filed 5–15–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute on Alcohol Abuse and Alcoholism Initial Review Group:

Purpose/Agenda: To review and evaluate grant applications.

Name of Committee: Clinical and Treatment Subcommittee.

Dates of Meeting: June 18–19, 1998.

Time: June 18, 8:30 a.m. to recess. June 19 8:30 a.m. to adjournment.

Place of Meeting: Holiday Inn Oceanfront, Palm Meeting Room, Hilton Head Island, South Carolina, 29938.

Contact Person: Elsie D. Taylor, 6000 Executive Blvd., Suite 409, Bethesda, MD 20892–7003, 301–443–9787.

Purpose/Agenda: To review and evaluate grant applications.

Name of Committee: Biochemistry, Physiology and Medicine Subcommittee.

Dates of Meeting: June 18–19, 1998.

Time: June 18, 3:30 p.m. to recess. June 19, 8:30 a.m. to adjournment.

Place of Meeting: Radisson Suite Resort, Hilton Head Island, 12 Park Lane, Hilton Head, South Carolina, 29928.

Contact Person: Ron Suddendorf, Ph.D., 6000 Executive Blvd., Suite 409, Bethesda, MD 20892–7003, 301–443–2926.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; and 93.891, Alcohol Research Center Grants; National Institutes of Health)

Dated: May 12, 1998.

Anna Snouffer,

Acting Committee Management Officer, NIH.

[FR Doc. 98–13149 Filed 5–15–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meetings:

Name of SEP: NIAID Malaria Research and Reference Reagent Repository.

Date: May 27, 1998.

Time: 8:00 a.m. to Adjournment.