Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD.

Contact Person: Kimberly Littleton Topper, 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, e-mail: *topperk@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512534. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21–756, pegaptanib sodium injection (proposed tradename, Macugen) by Eyetech Pharmaceuticals, Inc., indicated for the treatment of exudative (wet) age-related macular degeneration.

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 by August 13, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by August 13, 2004, 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.

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 Kimberly Littleton Topper 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: May 20, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–11946 Filed 5–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science; 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 Committee: Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science.

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

Date and Time: The meeting will be held on July 20 and 21, 2004, from 8:30 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Hilda Scharen, 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, e-mail: *SCHARENH@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 20, 2004, the subcommittee will address the following issues: (1) Receive topic updates for ongoing activities pertaining to manufacturing science and quality by design; and (2) discuss and provide comment on a Current Good Manufacturing Practice (cGMP) risk model being developed at FDA. On July 21, 2004, the subcommittee will address the following issues: (1) Discuss and provide comments on a cGMP and quality system approach for the production of investigational new drugs (INDs) and (2) discuss and provide comments on manufacturing science and risk-based questions for new drug application chemistry, manufacturing and controls (NDA CMC) review process.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by July 13, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on July 20, 2004, and between approximately 11:30 a.m. and 12 noon on July 21, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 13, 2004, 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.

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 Hilda Scharen 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: May 20, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–11945 Filed 5–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERIVCES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain copy of the data collection plans and draft instruments, call the

HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Ryan White Comprehensive AIDS Resources Emergency (CARE) Act: CARE Act Data Report (CADR) Form: (OMB No. 0915–0253)—Revision.

The CARE Act Data Report (CADR) form was created in 1999 by HRSA's HIV/AIDS Bureau. It is designed to collect information from grantees and their subcontracted service providers, who are funded under Titles I, II, III, and IV of the Ryan White CARE Act of 1990, as amended by the Ryan White CARE Act Amendments of 1996 and 2000 (codified under Title XXVI of the Public Health Services Act). All Titles of the CARE Act specify HRSA's responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of the quantity and quality of care. Accurate records of the providers receiving CARE Act funding, the services provided, and the clients served continue to be critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities. CARE Act grantees are required to report aggregate data to HRSA annually. The CADR form is used by grantees and their subcontracted service providers to report data on seven different areas: service provider information, client information, counseling and testing services, medical services, and other services provided/clients served, demographic information, and the Health Insurance Program. The primary purposes of the CADR are to: (1) Characterize the organizations from which clients receive services; (2) provide information on the number and characteristics of clients who receive CARE Act services; and (3) enable HAB to describe the type and amount of services a client receives. In addition to meeting the goal of accountability to the Congress, clients, advocacy groups, and the general public, information collected on the CADR is critical for HRSA, State, and local grantees, and individual providers to assess the status of existing HIV-related service delivery systems.

The response burden for grantees is estimated as:

Title under which grantee is funded	Number of grantee respondents	Responses per grantee	Hours to coordinate receipt of data reports	Total hour burden
Title I Only	51	1	40	2,040
Title II Only	59	1	40	2,360
Title III Only	365	1	20	7,300
Title IV Only	90	1	20	1,800
Subtotal	565			13,500

The response burden for service providers is estimated as:

Title under which grantee is funded	Number of respondents	Responses per provider	Hours per response	Total hour burden
Title I Only	976	1	26	25,376
Title II Only	857	1	26	22,282
Title III Only	166	1	44	7,304
Title IV Only	122	1	42	5,124
Funded under more than one title	681	1	50	34,050
Subtotal	2,802			94,136
Total for providers and grantees	3,367			107,636

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 20, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–12012 Filed 5–26–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National