

Research Working With Stakeholders on Scientific Opportunities for Facilitating Development of Vaccines, Blood and Blood Products, and Cellular, Tissue, and Gene Therapies.” The goal of the public workshop is to provide a forum for stakeholders to discuss opportunities for and potential approaches to the development of innovative scientific knowledge and tools to facilitate the development and availability of new biological products including vaccines, blood and blood products, and cellular, tissue, and gene therapies.

Date and Time: The public workshop will be held on October 7, 2004, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at The Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Melanie Whelan, Center for Biologics Evaluation and Research (HFM-43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-3841, FAX: 301-827-3079, e-mail: Whelan@cber.fda.gov.

Registration: Mail, fax, or e-mail the registration information (including name, title, affiliation, address, and telephone and fax numbers) to Melanie Whelan (see *Contact Person*) by September 30, 2004. Because seating is limited, we recommend early registration. There is no registration fee for the workshop. If you need special accommodations due to a disability, please contact Melanie Whelan (see *Contact Person*) at least 7 days in advance.

Comments: Regardless of attendance at the public workshop, interested persons may submit to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 written or electronic comments by September 23, 2004. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit a single copy of electronic comments or two copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION: The goal of this workshop is to provide a public forum for input and discussion concerning opportunities for the enhancement of scientific knowledge and tools for safety, efficacy, and product quality that can be used to more

effectively and efficiently develop and evaluate new biological products in the areas described.

On March 16, 2004, FDA released a report addressing the recent slowdown in innovative medical therapies submitted to FDA for approval entitled “Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products” at <http://www.fda.gov/oc/initiatives/criticalpath/>. That report describes the urgent need to create the scientific and technological “tools” to modernize the medical product development process—the Critical Path—to make medical product development more predictable and less costly.

The Center for Biologics Evaluation and Research (CBER) is seeking input from government and nongovernment research organizations, medical professional organizations, health care practitioners, patients, disease interest groups, pharmaceutical and biological product manufacturers and their industry organizations, and others with interests in facilitating development of the biological products that CBER regulates. The workshop will cover delineation of opportunities in key technologies and medical science knowledge needed to contribute to science based evaluation of the safety and efficacy of those biological products, and innovative development processes to manufacture them. FDA will discuss and welcomes input concerning all applicable areas of science including, but not limited to, bench laboratory investigations, clinical research and clinical trial design and execution, facility and manufacturing process research, statistical and epidemiological research, and computer science and computer modeling research. The workshop will not cover discussions of biological product discovery and invention or regulatory policies. The workshop will include presentations by FDA speakers and breakout sessions with panels composed of both FDA staff and non-FDA stakeholders, with an opportunity for public questions and comments.

FDA will post the agenda for this public workshop, when finalized on CBER’s Web sites at <http://www.fda.gov/cber/scireg.htm> and <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Transcripts: Please note that transcripts of the workshop will not be prepared.

Dated: August 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-19778 Filed 8-30-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Veterinary Medicine 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 Committee: Veterinary Medicine Advisory Committee.

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

Date and Time: The meeting will be held on October 13, 2004, from 8:30 a.m. to 5 p.m.

Location: DoubleTree Hotel, Plaza III, 1750 Rockville Pike, Rockville, MD.

Contact Person: Aleta Sindelar, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4515, e-mail: asindela@cvm.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512548, for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on the microbial food safety of an antimicrobial drug application currently under review for use in food-producing animals in accordance with the Center for Veterinary Medicine’s guidance for industry #152.

The background material for this meeting will be posted on the Internet no later than 1 business day before the meeting at <http://www.fda.gov/cvm/default.html>. A limited number of paper copies of the background information will be available at the registration table.

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 October 1, 2004. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by October 1, 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 Aleta Sindelar 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: August 24, 2004.

Lester M. Crawford,

Acting Commissioner for Food and Drugs.

[FR Doc. 04-19779 Filed 8-30-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Requested; Outcome Evaluation of the Small Grants Program for Behavioral Research in Cancer Control

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection:

Title: Outcome Evaluation of the Small Grants Program for Behavioral Research in Cancer Control.

Type of Information Collection Request: New.

Need and Use of Information Collection: The Small Grants Program support projects that can be completed in a short period of time, such as pilot projects, development and testing of new methodologies, secondary data analyses, or innovative studies that provide a basis for more extended research. This evaluation is being conducted to identify progress of this

program in establishing a cohort of scientists with a high level of research expertise in behavioral research cancer control. A primary objective of this study is to determine if the program's small grants R03 funding mechanism is effective in attracting investigators to the field of behavioral research and if so, what impact does the program have on the career of successful applicants. The findings will provide valuable information regarding (1) effectiveness of the program in attracting investigators to the field; (2) the impact of the program on investigators' careers; and (3) the overall benefit provided by the program through the R03 funding mechanism and assist the agency in determining whether changes to the program are necessary in future.

Frequency of Response: On occasion.

Affected Public: Individuals; teaching institutions or other non-profit.

Type of Respondents: Grantees funded under PAR 99-006 (n=80).

Type of Respondents: Principal Investigator awarded grants funded by PAR 00-006 (Dec. 1999-Nov. 2001).

Estimated Number of Respondents: 80.

Estimated Number of Responses per Respondent: 1.

Average Burden Hours per Response: .75.

Estimated Total Annual Burden Hours Requested: 60.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Principal Investigators awarded grants funded by PAR 99-006 (Dec. 1999-Nov. 2001)	80	1	0.75	60.0
Total				60.0

There is no cost to respondents. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) 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) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the

collection of information on those who are able to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Veroncia Chollette, RN, MS program Director, Applied Cancer Screening Research Branch, Behavioral Research Program Division of Cancer Control and Population Sciences, National Cancer Institute, 6130 Executive Blvd., Room 4100, Rockville, MD 20852 or call non-toll free number (301) 435-2837 or e-mail your request to: vc24a@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: August 20, 2004.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 04-19853 Filed 8-30-04; 8:45 am]

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