above, ZOLOFT Tablets, 150 mg and 200 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ZOLOFT Tablets, 150 mg and 200 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ZOLOFT Tablets, 150 mg and/or 200 mg, may be approved by the agency.

Dated: September 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–21022 Filed 9–16–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs 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: Anti-Infective Drugs 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 14, 2004, from 8 a.m. to 4:30 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Shalini Jain, 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: *jains@cder.fda.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the following topics: (1) Issues related to clinical trial design and analysis in studying catheter-related bacteremia and (2) issues related to clinical trial design and analysis in studying bacteremia due to staphylococcus aureus. Background materials for this meeting will be posted on the Internet 1 business day before the meeting at: *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*.

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 4, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 4, 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 Shalini Jain 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: September 9, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–20935 Filed 9–16–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Advisory Committee for Pharmaceutical Science.

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 19 and 20, 2004, from 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee conference 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, FAX: 301–827–6776, e-mail: SCHARENH@cder.fda.gov, or FDAAdvisory 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 October 19, 2004, the committee will do the following: (1) receive updates pertaining to the Manufacturing Subcommittee, the Parametric Tolerance Interval Test (PTIT) Workgroup, and the Good Manufacturing Practices (GMPs) for the 21st Century Initiative, and (2) review and discuss research opportunities under the Critical Path Initiative. On October 20, 2004, the committee will do the following: (1) review and discuss the Office of Pharmaceutical Science (OPS) plans and activities designed to take the organization towards the ''desired state'' of science and risk-based regulatory policies and practices as articulated under the GMPs for the 21st Century Initiative, and (2) review and discuss specific topics related to pharmaceutical equivalence and bioequivalence of generic drugs.

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 12, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 12, 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: September 9, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–20934 Filed 9–16–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Submission for OMB Review, Comments Request; Improving Media Coverage of Cancer: A Survey of Science and Health Reporters

SUMMARY: In compliance with the requirement of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 11, 2004, page 11638 and allowed 60 days for public comment. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Improving Media Coverage of Cancer: A Survey of Science and Health Reporters.

Type of Information Collection Request: New.

Need and Use of Information Collection: The NCI is dedicated to improving the extent and quality of cancer coverage in all forms of news media. Towards this goal, the NCI would like to explore how health stories are currently being covered in print, television, and radio news coverage and would also like to understand the barriers that exist to better health and cancer coverage. Information from this research can be used to support the myriad of efforts and initiatives of the NCI as described in the Bypass Budget to ''understand and apply the most effective communications approaches to maximize access to and use of cancer information by all who need it.'' The primary objective of the NCI Media survey of reporters and editors covering health and medical science news stories in the U.S. is to gain knowledge of their background, environment, perspectives, and training needs in an effort to develop initiatives that will improve news media reportage of health in general and cancer in particular. Six hundred reporters and editorial personnel of daily and weekly newspapers, magazines, wire service agencies, and television and radio stations with a specific focus on health and medical science reporting will be surveyed to determine their socio-demographic characteristics, individual characteristics, occupational practices, and other organizational and environmental factors that influence how they report health and medical science stories. This information will allow NCI to assess reporters' training needs, the barriers they face, and the resources NCI can develop to assist them in reporting cancer-related stories.

Frequency of Response: Once.

Affected Public: Individuals and businesses.

Type of Respondents: Reporters and editors.

The annual reporting burden is as follows:

Estimated Number of Respondents: 600;

Estimated Number of Responses per Respondent: 1;

Average Burden Hours per Response: .25; and

Estimated Total Annual Burden Hours Requested: 150.

The total estimated cost to respondents is $2,838. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Reporters	600	1	.25	150
Total				150

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Helen I. Meissner, PhD, Chief, Applied Cancer Screening Research Branch, Behavioral Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute, Executive Plaza North, Suite 4102, 6130 Executive Boulevard, MSC 7331, Bethesda, MD 20892–7331, or call non-toll-free