and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 28, 1997, 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 required to make their comments.

Open committee discussion. The committee will discuss and vote on a premarket approval application for a hyaluronic acid coating solution used to reduce adhesions resulting from incidental tissue damage during abdominal and pelvic surgery.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: April 15, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–10212 Filed 4–16–97; 12:52 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission of OMB Review; Comment Request; Women's Health Initiative Observational Study

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995, the Office of the Director (OD), 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 November 4, 1996 (Volume 61, Number 214, Page 56696) and allowed 60-days for public comment. No public comments were received. 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:* Women's Health Initiative (WHI) Observational Study. *Type of Information Collection Request:* Revision of OMB #0925–0414. Exp: 6/30/97. *Need for Use of Information Collection:* This study will be used by NIH to evaluate risk factors for chronic disease among older women by developing and following a large cohort of postmenopausal women and relating subsequent disease development to baseline assessments of historical, physical, psychosocial, and physiologic characteristics. In addition, the observational study will complement the clinical trial (which has received clinical exemption) and provide additional information on the common cause of frailty, disability and health for postmenopausal women, namely, coronary heart disease, breast and colorectal cancer, and osteoporotic fractures. *Frequency of Response:* On occasion. *Affected Public:* Individuals and physicians. *Type of Respondents:* Women, next of kin, and physicians. The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual hours requested
OS Participants	100,000	1.06667	.819	87,360
Next-of-Kin	2,682	1	.0835	224
Physician	166	1	.0835	14
Total				87,598

The annualized cost to respondents is: $876,525.

There are no annual Capital Costs, Operating Costs, and/or Maintenance Costs to report.

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 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.

Direct Comments to OMB

Written comments and/or suggestions regarding 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, D.C. 20503, Attention: Desk Officer for NIH. to request more information on the proposed project or to obtain a copy of the data collection plan and instruments, contact: Dr. Loretta Finnegan, Women's Health Initiative Program Office, 7550 Rockville Pike, Room 6A09, Bethesda, Maryland 20892–9110 or call non-toll-free number (301) 402–2900, or E-mail your request, including your address to: <FinnegaL@od31em1.od.nih.gov>.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before May 19, 1997.

Dated: March 11, 1997.

Stephen Benowitz,

Executive Officer, Office of the Director, NIH.

[FR Doc. 97–9993 Filed 4–17–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of 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 National Cancer Institute Frederick Cancer Research and Development Center Advisory Committee.

The open portion of the meeting will be limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person in advance of the meeting.

Committee Name: Frederick Cancer Research and Development Center Advisory Committee.

Date: June 9–10, 1997.

Place: Frederick Cancer Research and Development Center, Building 549, Executive Board Room, Frederick, Maryland.

Open: June 9—8:30 a.m.–10:00 a.m.

Agenda: Discussion of administrative matters such as future meetings, budget, and information items related to the operation of the NCI Frederick Cancer Research and Development Center.

Closed: June 9—10 a.m. to recess; June 10–8:30 a.m. to adjournment.

Agenda/Purpose: Discussion of previous site visit report and response for the Molecular Virology and Carcinogenesis Laboratory review held December 17–18, 1996. The majority of the closed session will be devoted to a site review of the Gene Regulation and Chromosome Biology Laboratory with ABL-Basic Research Program Contract. Also included is a re-review of the Molecular Aspects of Drug Design Section, Macromolecular Structure Laboratory with ABL-Basic Research Program Contract.

Contact Person: Cedric W. Long, Ph.D., Frederick Cancer Research and Development Center, P.O. Box B,