OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: June 19, 1996.

Larry Guerrero,

Director, Office of Information Management Services.

[FR Doc. 96–16070 Filed 6–24–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. July 10 and 11, l996, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Closed committee deliberations, July 10, l996, 8 a.m. to 10 a.m., open committee discussion, 10 a.m. to 3:45 p.m.; open public hearing, 3:45 p.m. to 4:30 p.m., unless public participation does not last that long; closed committee deliberations, July 11, 1996, 8 a.m. to 8:45 a.m.; open committee discussion, 8:45 a.m. to 12 m.; open public hearing, 12 m. to 12:30 p.m., unless public participation does not last that long; open committee discussion, 12:30 p.m. to 2 p.m.; closed committee deliberations, 2 p.m. to 3:30 p.m.; Nancy T. Cherry or Sandy M. Salins, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

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 July 3, 1996, 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. On July 10, 1996, the committee will review safety and efficacy data pertaining to a diphtheria/tetanus/acellular pertussis vaccine manufactured by SmithKline Beecham. On July 11, 1996, the committee will review safety and comparative immunogenicity data pertaining to a liquid version of an Haemophilus b conjugate vaccine manufactured by Merck & Co. The committee will also hear a briefing on proposed changes in the polio vaccine recommendations, and a briefing on a research program in the Division of Viral Products.

Closed committee deliberations. On July 10 and 11, l996, the committee will review trade secret and/or confidential commercial information relevant to pending product licensing applications or amendments. These portions of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)). On July 11, l996, the committee will also review data of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(6)).

Circulatory System Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 15, 1996, 7:30 a.m., Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Courtyard by Marriott, 2500 Research Blvd., Rockville, MD. Attendees requiring overnight accommodations may contact the hotel at 301–670–6700, and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Shirley Meeks, Conference Management, 301–594–1283, ext. 113. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Closed committee deliberations, 7:30 a.m. to 8:30 a.m.; open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 3:30 p.m.; Ramiah Subramanian, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Circulatory System Devices Panel, code 12625. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices 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 July 1, 1996, 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 (PMA) for a pacemaker lead. The committee will also discuss issues related to the draft guidance for Automatic Implantable Pacer Cardioverter Defibrillator (AIPCD) submissions, primarily focusing on new suggested labeling changes. Single copies of the draft guidance document are available from the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 1–800–638–2041 or 301–443–6597.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information relevant to investigational device exemption applications and PMA's for cardiovascular system devices. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 25, 1996, 8:30 a.m., Gaithersburg Hilton, Ballroom, 620 Perry Pkwy., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–977–8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Shirley Meeks, Conference Management, 301–594–1283, ext. 113. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 4 p.m.; closed committee deliberations, 4 p.m. to 5 p.m.; Mary J. Cornelius, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd. Rockville, MD 20850, 301–594–2194, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Gastroenterology and Urology Devices Panel, code 12523. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices 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 July 16, 1996, 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 general issues related to a premarket approval application for a device intended to manage female urinary incontinence.

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

Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 26, 1996, 8:30 a.m., Gaithersburg Hilton, Ballroom, 620 Perry Pkwy., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–977–8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Joanne Choy, Conference Management, 301–594–1283, ext. 105. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Closed presentation of data, 8:30 a.m. to 9 a.m.; open committee discussion (first session), 9 a.m. to 10:30 a.m.; open public hearing, 10:30 a.m. to 11:30 a.m., unless public participation does not last that long; open committee discussion (second session), 11:30 a.m. to 5 p.m.; Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Ophthalmic Devices Panel, code 12396. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices 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 July 12, 1996, 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. First Session—The Vitreoretinal and Extraocular Devices Branch will present a summary report of public comments received on the proposed rule that published in the Federal Register of April 1, 1996 (61 FR 14277), for reclassification of contact lens care products. The committee will review and recommend the classification status for currently unclassified devices which may include corneal storage media and external eyelid weights. Second Session—FDA staff will present to the committee the regulatory status of lasers for the correction of refractive error currently in use in the United States and FDA's policies and regulations regarding those lasers.

Closed presentation of data. FDA staff will present to the committee trade secret and/or confidential commercial information relevant to investigational device exemption applications and premarket approval applications. 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 each meeting 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: June 19, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–16174 Filed 6–24–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Project Grants for Renovation or Construction of Non-Acute Health Care Facilities

AGENCY: Health Resources and Services Administration.

ACTION: Correction.

SUMMARY: The Notice of Availability of Funds, Project Grants for Renovation or Construction of Non-Acute Health Care Facilities, which was published on June 13, 1996, at 61 FR 30077, is corrected to include the following areas in Puerto Rico that were not on the original list:

Appendix I—Metropolitan Areas

Puerto Rico (part):
- Loiza Municipio
- Luquillo Municipio
- Manati Municipio
- Mayaguez Municipio
- Moca Municipio
- Naranjito Municipio
- Ponce Municipio
- Quebradillas Municipio
- Rio Grande Municipio
- San German Municipio
- San Juan Municipio
- San Lorenzo Municipio
- Toa Alta Municipio
- Toa Baja Municipio
- Trujillo Alto Municipio
- Vega Alta Municipio
- Vega Baja Municipio

Dated: June 20, 1996.

Ciro V. Sumaya,

Administrator.

[FR Doc. 96–16183 Filed 6–24–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as