FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before November 18, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 4, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–26683 Filed 10–17–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the National Mammography Quality Assurance Advisory Committee, which is scheduled for October 21, 22, and 23, 1996. This meeting was announced in the Federal Register of September 24, 1996 (61 FR 50031 at 50033). The amendment is being made to add a closed session to the agenda scheduled for October 23, 1996. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 24, 1996, FDA announced that a meeting of the National Mammography Quality Assurance Advisory Committee would be held on October 21, 22, and 23, 1996.

On page 50033, in the first column, the ''*Type of meeting and contact person*'' portion is amended as follows:

Type of meeting and contact person. Open public hearing, October 21, 1996, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; open committee discussion, October 22, 1996, 9 a.m. to 5 p.m.; open committee discussion, October 23, 1996, 8 a.m. to 10 a.m.; closed committee deliberations, 10 a.m. to 10:30 a.m.; open committee discussion, 10:30 a.m. to 5 p.m.; Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), National Mammography Quality Assurance Advisory Committee, code 12397.

On page 50033, in the second column, in addition to the open committee discussion of the request of the American Board of Certification in Radiology to be designated as eligible to certify interpreting physicians under the Mammography Quality Standards Act (the MQSA), a ''*Closed committee deliberations*'' portion is added as follows:

Closed committee deliberations. On October 23, 1996, the committee will discuss confidential commercial information submitted in connection with the request of the American Board of Certification in Radiology to be designated as eligible to certify interpreting physicians under the MQSA. 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: October 15, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–26915 Filed 10–16–96; 12:37 pm]

BILLING CODE 4160–01–F

[Docket No. 95S–0181]

Mutual Recognition Agreement (MRA); Public Meeting; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and availability of draft document.

SUMMARY: The Food and Drug Administration (FDA) (Office of External Affairs, Office of International Affairs; Office of Policy; Office of Operations, Office of Regulatory Affairs; and the Centers for Biologics Evaluation and Research, Drug Evaluation and Research, and Veterinary Medicine) is announcing a public meeting to provide information about discussions with the European Union (EU) related to a possible agreement to exchange inspectional information on good manufacturing practices and quality controls for human biologicals and human and animal drugs. At a meeting held on March 31, 1995, FDA committed to keeping the public informed about the progress of these negotiations and to receiving comments on FDA's proposal for an MRA. FDA is also announcing the availability of the document entitled ''FDA Proposal for an Agreement With the European Union Concerning the Mutual Recognition of Inspections to Determine Adherence to Good Manufacturing Practices for Pharmaceuticals Including Biologicals.''

DATES: The public meeting will be held on Wednesday, October 30, 1996, from 9 a.m. to 1 p.m. Those persons interested in attending this meeting must fax their registration, including name(s), firm/organization name, address, and telephone and fax number by October 25, 1996, to Nathaniel L. Geary (address below). Those persons interested in making a presentation at this meeting must contact Nathaniel L. Geary (address below) by October 25, 1996. There is no registration fee for this meeting, but advance registration is required. Space is limited and all interested parties are encouraged to register early. Written comments may be submitted at any time.

ADDRESSES: The public meeting will be held at the Parklawn Bldg., conference room E, 5600 Fishers Lane, Rockville, MD 20857.

Submit written requests for single copies of ''FDA Proposal for an Agreement With the European Union Concerning the Mutual Recognition of Inspections to Determine Adherence to Good Manufacturing Practices for Pharmaceuticals Including Biologicals'' to Walter M. Batts or Merton V. Smith (address below). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on ''FDA Proposal for an Agreement With the European Union Concerning the Mutual Recognition of Inspections to Determine Adherence to Good Manufacturing Practices for Pharmaceuticals Including Biologicals'' to Merton V. Smith (address below). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of ''FDA Proposal for an Agreement with the European Union Concerning the Mutual Recognition of Inspections to Determine Adherence to Good Manufacturing Practices for Pharmaceuticals Including Biologicals'' and received comments may be seen at the Dockets Management Branch between 9 a.m and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

For information regarding registration: Nathaniel L. Geary, Industry and Small Business Liaison Staff (HF–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3375, FAX 301–443–5153.

For information regarding comments: Walter M. Batts or Merton V. Smith, Office of International Affairs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480, FAX 301–443–0235.

SUPPLEMENTARY INFORMATION: Joint discussions between the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, and the FDA with the EU, were disclosed in a public meeting held in Washington, DC on March 31, 1995. FDA is interested in the views of industry and other interested parties on its approach to negotiating an MRA with the EU. It would be useful for FDA to receive comments on the following issues: What effect will such an agreement have upon importation and exportation of those drug and biological products which would be covered by an MRA? What effect on product safety or other product-related matters, if any, do industry and other interested parties perceive to result from entering into an MRA?