FDA did not place in the public docket trade secret and confidential commercial information, or information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. An index listing these documents was created by the agency and is available to the public. However, unless the information in these documents was inextricably intertwined with the other information contained in the document, FDA redacted the trade secret, confidential commercial, or privacy information and placed the remainder of the document in the public docket.

In addition, FDA did not include in the public docket certain documents developed during the course of the agency's investigation of the tobacco industry because these documents could disclose the identity of sources that furnished information to the agency on a confidential basis. The agency's policy with respect to confidential sources in this investigation was discussed at the hearings before the House Subcommittee on Health and the Environment (see Regulation of Tobacco Products (Part 1) (March 25, 1994), pp. 35–37; Regulation of Tobacco Products (Part 3) (June 21, 1994), pp. 87–96).

In the agency's view, there can be no reasonable expectation of confidentiality for information submitted to a public docket in a rulemaking proceeding. Therefore, an agency is under no legal obligation to scrutinize documents submitted to a public docket to determine whether they may contain proprietary information. However, because it is aware of the sensitivity and importance of such information, FDA has long followed certain procedures to try to ensure that clearly proprietary information is not unwittingly made available to the public. FDA scans documents submitted to a docket for obvious trade secrets (e.g., formulas) or personal privacy information. In addition, any document marked confidential is referred to the appropriate Center Freedom of Information Act officer for a determination as to whether it would be exempt from public disclosure under Exemption 4 of the Freedom of Information Act (trade secrets and commercial or financial information obtained from a person and privileged or confidential). Before documents containing such information are placed on the record, the Center consults with the submitter to determine whether the submitter intended to make the document publicly available by placing it on the record. The agency is following these procedures in the tobacco proceeding.

Dated: December 21, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–31368 Filed 12–22–95; 11:18 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting 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.

MEETING: The following advisory committee meeting is announced:

Subcommittee Meeting of the National Mammography Quality Assurance Advisory Committee

Date, time, and place. January 10 and 11, 1996, 9 a.m., Hyatt Regency—Bethesda, Baccarat Suite, One Bethesda Metro Center, Bethesda, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–657–1234, and reference the FDA Committee meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, January 10, 1996, 9 a.m. to 10 a.m., unless public participation does not last that long; open subcommittee discussion, 10 a.m. to 5 p.m.; open subcommittee discussion, January 11, 1996, 9 a.m. to 1 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.

General function of the committee. The committee advises on developing appropriate quality standards and regulations for the use of mammography facilities.

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 January 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 subcommittee discussion. On January 10 and 11, 1996, the Access to Mammography Services subcommittee will meet. The subcommittee will discuss the ongoing work which is necessary to make the determinations and subsequently prepare the reports as mandated in the Mammography Quality Standards Act. Upon completion, the subcommittee report will be reviewed by the committee prior to submission to the Secretary and Congress.

FDA public advisory committee meetings 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. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open 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