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, rm. 12A–16, 5600 Fishers Lane, 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, rm. 1–23, 12420 Parklawn Dr., 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.

This notice is issued under section 10(a)(1) and (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: December 18, 1995.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 95–31293 Filed 12–26–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–253S]

Procedures for Handling Confidential Information in Rulemaking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a statement regarding the procedures generally followed by the agency with respect to the use of confidential commercial information, trade secrets, and other confidential or sensitive information during rulemaking. In brief, FDA does not place into a public docket trade secret, confidential commercial information, or information whose disclosure would constitute a clearly unwarranted invasion of privacy or would reveal the identity of confidential sources. FDA tries to assure that clearly proprietary information is not unwittingly made available to the public, but also advises that information submitted to a public docket during a rulemaking proceeding does not carry a reasonable expectation of confidentiality.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION: FDA has received several inquiries regarding certain information that FDA used in developing the proposed rule and notice pertaining to nicotine-containing cigarettes and smokeless tobacco products. The proposed rule, entitled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents,'' and an accompanying document entitled ''Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act,'' appeared in the Federal Register on August 11, 1995 (60 FR 41314 and 60 FR 41453 at 41454, respectively). In general, the cigarette and smokeless tobacco companies have questioned or sought to limit FDA's ability to use or to receive certain information, particularly documents that were prepared by industry officials but not submitted by the industry to FDA during rulemaking.

In response, the agency has developed a statement describing the procedures generally followed by the agency with respect to confidential information in a rulemaking docket. In brief, FDA does not place trade secret, confidential commercial information, or information whose disclosure would constitute a clearly unwarranted invasion of privacy or would reveal the identity of confidential sources, into a public docket. FDA tries to assure that clearly proprietary information is not unwittingly made available to the public, but also advises that information submitted to a public docket during a rulemaking proceeding does not carry a reasonable expectation of confidentiality.

Although the agency has developed this written statement to address concerns raised in the tobacco proceedings, the positions expressed in the statement reflect docket management procedures that the agency has long used in other rulemaking proceedings. Consequently, FDA is publishing the statement in the Federal Register.

The statement is as follows:

Statement of Procedures for Handling Confidential Information in Rulemaking

FDA has received several inquiries regarding the agency's procedures for handling confidential information in the dockets compiled for the agency's proposed regulation restricting the sale and distribution of cigarettes and smokeless tobacco products to protect children and adolescents, and the accompanying legal analysis and factual findings, both of which were published in the Federal Register on August 11, 1995. This notice describes the procedures followed by FDA generally with respect to confidential information in a rulemaking docket.

FDA compiled the docket for the proposed regulation restricting the sale and distribution of cigarettes and smokeless tobacco products to protect children and adolescents (the proposed rule) and the document entitled ''Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act'' (the document) in accordance with the requirements of the Administrative Procedure Act, 5 U.S.C. 551, *et seq.* (APA), and FDA's existing regulations at 21 CFR 10.40. This docket includes existing factual information and submitted information relied upon by the agency decisionmakers in support of the analysis and the proposed rule. The agency has also included in the docket factual material and submitted information considered by agency decisionmakers, except for the limited group of documents discussed below.

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