completing the collection of information. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing the burden, to: DHHS Reports Clearance Officer, Paperwork Reduction Project (0910–0320), Hubert Humphrey Bldg., 200 Independence Ave. SW., rm 531–H, Washington, DC 20201. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number.

Submit written information for inclusion on the EC list to Marilyn F. Balmer (address above).

Submit written comments on the best mechanisms to be used in obtaining future changes and additions to the EC lists for dairy products, shell eggs, game meat and game meat products to the Dockets Management Branch (address above). All comments should be identified with the docket number found in the brackets in the heading of this document.

Dated: March 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8360 Filed 4–1–96; 3:24 pm]

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:

–Nonprescription Drugs Advisory Committee With Representation From the Drug Abuse Advisory Committee

–Date, time, and place. April 19, 1996, 8:30 a.m., Holiday Inn—Silver Spring, Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

–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 11:30 a.m.; closed presentation of data, 11:30 a.m. to 12 m.; open committee discussion, 12 m. to 3 p.m.; closed presentation of data, 3 p.m. to 3:30 p.m.; open committee discussion, 3:30 p.m. to 5 p.m.; Kennerly K. Chapman, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or Liz Ortuzar (address above), 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541 or the Drug Abuse Advisory Committee, code 12535.

General function of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Drug Abuse Advisory Committee advises on the scientific and medical evaluation of information gathered by the Department of Health and Human Services and the Department of Justice on the safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs.

–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 5, 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 new drug application (NDA) 20–536, Nicotrol® (nicotine transdermal system, Pharmacia Upjohn/McNeil Consumer Products) indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms, to switch from prescription to over-the-counter status; and supplemental NDA 20–165/S–011 Nicoderm® (nicotine patch, Hoescht Marion Roussel/Alza Corp.), indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms, to switch from prescription to over-the-counter status.

–Closed presentation of data. The committee will hear trade secret and/or confidential commercial information. 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, 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.

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 (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: March 29, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–8246 Filed 4–3–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95P–0110]

Guidance Documents; The Food and Drug Administration's Development and Use; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on issues relating to the agency's development and use of guidance documents. The agency is holding this public meeting to further discuss issues that were raised in a citizen petition submitted by the Indiana Medical Devices Manufacturers Council, Inc. (IMDMC). The citizen petition requested that FDA control the development of guidance documents by written procedures that ensure the appropriate level of meaningful public participation.

DATES: The public meeting will be held on Friday, April 26, 1996, 9 a.m. to 3 p.m.

ADDRESSES: The public meeting will be held at the National Institutes of Health, Warren Grant Magnuson Clinical Center, Bldg. 10, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD 20892–1162. Those persons interested in attending this meeting should FAX their registration to Lisa Barclay by April 16, 1996.

The notice of registration should include the registrant's name, address, telephone number, FAX number, and business affiliation, if any. Persons interested in making a presentation at the meeting should include a brief summary of the presentation, and the approximate amount of time requested for the presentation. FDA will allocate the time available for the public meeting among the persons who properly file notices of their intent to make a presentation at the meeting. If time permits, FDA may allow additional presentations from interested persons attending the meeting who did not submit a notice of their intent to make a presentation.

Notices of registration should be received by April 16, 1996. There is no registration fee for this public meeting, but advance registration is required. Interested parties are encouraged to register early.

Parking in the Clinical Center visitor area is reserved for Clinical Center patients and their visitors. If you must drive, please use an outlying parking lot, such as Lot 41B. Free shuttle bus service is provided from Lot 41B to the Clinical Center every 8 minutes during rush hour and every 15 minutes at other times. The National Institutes of Health campus may be reached by subway (Metro). Take the Red Line to the Medical Center stop. The same shuttle service is available from Metro to the Clinical Center.

FOR FURTHER INFORMATION CONTACT: Lisa Barclay, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, rm. 14–101, Rockville, MD 20857, 301–827–3360, FAX 301–594–6777.

SUPPLEMENTARY INFORMATION: Issues relating to FDA's development and use of guidance documents were raised in a citizen petition submitted by the IMDMC. (See Docket No. 95P–0110). Specifically, the petition requested that FDA control the initiation, development, and issuance of guidance documents by written procedures that ensure the appropriate level of