(21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 22, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–13535 Filed 5–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Open Meeting for Representatives of Health Professional Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing an open meeting with representatives of health professional organizations. The meeting will be chaired by Sharon Smith Holston, Deputy Commissioner for External Affairs. This meeting will provide participants an opportunity to hear a discussion on prescription (Rx) to over-the-counter (OTC) switches and the new OTC proposed labeling initiative.

DATES: The meeting will be held on Thursday, May 29, 1997, from 1:30 p.m. to 4:30 p.m.

ADDRESSES: The meeting will be held at the Bethesda Holiday Inn, 8210 Wisconsin Ave., Bethesda, MD. Interested persons may register with Betty Palsgrove at 301–443–1652. Registrations also may be transmitted by FAX to 1–800–344–3332 or 301–443–2446.

FOR FURTHER INFORMATION CONTACT: Peter H. Rheinstein, Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5470.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide an opportunity for representatives of health professional organizations and other interested persons to be briefed by senior FDA staff and to provide an opportunity for informal discussion on the switching of drug products from prescription to OTC status and on FDA's proposed regulation for labeling of OTC drug products, which would amend 21 CFR parts 201, 330, and 358 (62 FR 9024, February 27, 1997).

This public meeting is free of charge; however, space is limited. Registration for the meeting will be accepted in the order received and should be sent to the contact person listed above. Registration should include the name and title of the person attending and the name of the organization being represented, if any.

Dated: May 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–13447 Filed 5–21–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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:

Science Advisory Board to the National Center for Toxicological Research

Date, time, and place. June 5 and 6, 1997, 9 a.m., Bldg. 12, conference room, National Center for Toxicological Research, Jefferson, AR.

Type of meeting and contact person. Open board discussion, June 5, 1997, 9 a.m. to 4:30 p.m.; open board discussion, June 6, 1997, 9 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m., unless public participation does not last that long; closed board deliberations, 12 m. to 1:30 p.m.; Ronald F. Coene, National Center for Toxicological Research (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3155, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Science Advisory Board to the National Center for Toxicological Research, code 12559. Please call the hotline for information concerning any possible changes.

General function of the board. The board advises on establishment and implementation of a research program that will assist the Commissioner of Food and Drugs to fulfill regulatory responsibilities.

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 May 26, 1997, 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 board discussion. The board will be presented with draft reports, for review and discussion, from two site visit review teams: (1) On the Estrogen Knowledge Base Program, and (2) on the Information Management Program. Staff from the Analytical Methods Program will provide a progress report on the recommendations made by the Science Advisory Board. Also there will be discussion of an agenda for future program review site visits, an update from the Director, and a review of the progress the agency has made in establishing the Arkansas Regional Laboratory at the Jefferson, AR site.

A final agenda will be available on June 3, 1997, from the contact person.

Closed board deliberations. The board will discuss personal information concerning individuals associated with the research programs at the center, disclosure of which 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)).

The Commissioner approves the scheduling of meetings at locations outside of the Washington, DC, area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

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.

FDA regrets that it was unable to publish this notice 15 days prior to the June 5 and 6, 1997, Science Advisory Board to the National Center for Toxicological Research meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Science Advisory Board to the National Center for Toxicological Research were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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: May 16, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–13448 Filed 5–21–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0153]

Accidental Radioactive Contamination of Human Food and Animal Feeds; Draft of Recommendations for State and Local Agencies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies.'' This draft guidance would replace the ''Accidental Contamination of Human Foods and Animal Feeds: Recommendations to State and Local Agencies'' issued in 1982 to State and local agencies responsible for taking protective actions in the event that an incident causes the contamination of