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

human food or animal feeds. This draft guidance is intended to assist FDA in fulfilling its responsibility to issue guidance on planning actions for evaluating and preventing contamination of human food and animal feeds and to issue guidance on the control and use of these products should they become contaminated. The agency requests comments on this draft guidance.

DATES: Written comments by August 20, 1997.

ADDRESSES: Submit written requests for single copies of ''Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies'' to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (address above). Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Donald L. Thompson, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–0012, FAX 301–594–4760.

SUPPLEMENTARY INFORMATION:

I. Background

In 1982, FDA issued recommendations on accidental radioactive contamination of human food and animal feeds. Since 1982, significant advancements related to emergency planning have warranted updating the guidance document. The draft guidance includes: New scientific information and radiation protection philosophy, experience gained since 1982, and guidance developed by international organizations. In 1992, and again in 1994, drafts of the revised document were circulated for review by the staff of the principal Federal agencies involved in radiological emergency response and by a committee of the Conference of Radiation Control Program Directors.

These recommendations are intended to provide guidance to State and local agencies to aid in emergency response planning and execution of protective actions associated with production, processing, distribution, and use of human food and animal feeds accidentally contaminated with radionuclides. Limits, called derived intervention levels, are set on the radionuclide activity concentration permitted in food, and protective actions for reducing the amount of contamination are discussed. The recommendations are applicable to accidents at nuclear power plants and many other types of accidents where a significant radiation dose could be received as a result of consumption of contaminated food. The recommendations do not authorize or apply to deliberate releases of radionuclides that could result in contamination, nor do they apply to situations of a nonaccidental nature. These recommendations would rescind and replace the 1982 FDA recommendations.

II. Significance of a Guidance

A guidance document does not bind FDA or the public, and it does not create or confer any rights, privileges, or benefits for, or on, any person; however, it does represent the agency's current thinking on the subjects discussed therein. The draft guidance announced in this document represents the agency's tentative thinking of the subjects discussed therein.

III. Request for Comments

Interested persons may, on or before August 20, 1997, submit to the Dockets Management Branch (address above) written comments on the ''Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies.'' 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 the draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m and 4 p.m. Monday through Friday.

Dated: May 12, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–13376 Filed 5–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0413]

Draft Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Germicides; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on the notice announcing the availability of a draft guidance, which was published in the **Federal Register** of December 6, 1996 (61 FR 64755), entitled ''Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Germicides.'' The draft guidance provides specific directions to manufacturers regarding information and data that should be submitted to FDA in a premarket notification (510(k)) submission for a liquid chemical germicide.

DATES: Written comments by August 20, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 6, 1996 (61 FR 64755), FDA announced the availability of a draft guidance entitled ''Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Germicides.'' The draft guidance provides specific directions to manufacturers regarding information and data that should be submitted to FDA in a premarket notification (510(k)) submission for a liquid chemical germicide. Interested persons were given until March 6, 1997, to submit written comments on the notice.

With the passage of the Food Quality Protection Act of 1996, the distribution of the draft guidance was delayed until it could be revised to reflect the regulatory changes. However, the revision has been more complex than