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 This draft guidance is intended to assist FDA in fulfilling its responsibility to issue guidance on planning actions for evaluating and preventing contamination of human food and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 The agency requests comments on this draft guidance.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 Submit written comments on the draft guidance to the Dockets Management Branch (address above).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 A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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 The draft guidance includes: New scientific information and radiation protection philosophy, experience gained since 1982, and guidance developed by international organizations.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

anticipated. Therefore, FDA has determined that the important health issues involved in the draft guidance provide good cause for reopening of the comment period on the original draft guidance in accordance with section 520(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(d)). FDA is reopening the comment period for an additional 90 days.

Interested persons may, on or before August 20, 1997, submit to the Dockets Management Branch (address above) written comments regarding the notice. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–13378 Filed 5–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0146]

A Primer on Medical Device Interactions With Magnetic Resonance Imaging Systems; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems.'' The purpose of this document is twofold. It should serve to sensitize medical device reviewers to the meaning and ramifications of magnetic resonance (MR) safety or MR compatibility claims. It will also provide for FDA reviewers a background of MR theory and the effect the MR environment may have on medical devices.

DATES: Submit written comments on the draft guidance document by August 20, 1997.

ADDRESSES: Requests for single copies of the draft guidance document and any 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: Marlene Skopec, Center for Devices and Radiological Health (HFZ–133), Food and Drug Administration, 12721 Twinbrook Pkwy., Rockville, MD 20852, 301–443–3840.

SUPPLEMENTARY INFORMATION: FDA recognizes that there is an increasing number of medical device manufacturers seeking to make MR safe or MR compatibility claims for their devices. It is important that medical device reviewers are aware of the potential implications of these claims. With the advent of open magnetic resonance imaging (MRI) systems and interventional MR, the trend of making MR claims for medical devices will continue and accelerate. This draft guidance document is intended to serve as a general background document on medical device interactions in MRI systems. It is not intended to replace documents created that address specific devices or device areas.

A guidance document does not bind FDA or the public, and 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 document announced in this notice represents the agency's tentative thinking of the subjects discussed therein.

Interested persons may, on or before August 20, 1997, submit to the Dockets Management Branch (address above) written comments on ''A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems.'' 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 Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems'' and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 21, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–13377 Filed 5–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Reinstatement, with change, of previously approved collection for which approval has expired; *Title of Information Collection:* Medicaid Report on Payables and Receivables; *Form No.:* HCFA–R–199; *Use:* The Chief Financial Officers Act of 1990 requires government agencies to produce auditable financial statements. Form R–199 will collect accounting data from the States on Payables and Receivables; *Frequency:* Annually; *Affected Public:* State, local or tribal government; *Number of Respondents:* 57; *Total Annual Responses:* 57; *Total Annual Hours:* 171.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Linda Mansfield, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.