DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0153]

Guidance on Accidental Radioactive Contamination of Human Food and Animal Feeds: 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 guidance entitled ''Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations to State and Local Agencies.'' This guidance will replace the ''Accidental Radioactive 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. FDA has a responsibility to issue guidance on planning actions for evaluating and preventing contamination of human food and animal feeds and on the control and use of these products should they become contaminated.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance entitled ''Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendation for State and Local Agencies'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the guidance to the contact person listed below. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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.

SUPPLEMENTARY INFORMATION:

I. Background

Recommendations on accidental radioactive contamination of human food and animal feeds were issued in 1982 by FDA. Since then, there have been enough significant advancements related to emergency planning to warrant updating the guidance document. New scientific information and radiation protection philosophy are incorporated, experience gained since 1982 is included, and guidance developed by international organizations is taken into account. In 1992, and again in 1994, drafts of the revised document were circulated for review by staff of the principal Federal agencies involved in radiological emergency response and by a committee of the Conference Radiation Control Program Directors. In the **Federal Register** of May 22, 1997 (62 FR 28055), FDA published a notice of availability of a draft guidance. Interested persons were given until August 20, 1997, to comment on the draft. Forty-two comments were received, principally from State and Federal agencies. Revision of the draft in response to comments did not involve any change in concepts, only clarifications, errata, and definitions.

The recommendations 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 nonaccidental nature. These recommendations rescind and replace the 1982 recommendations.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the guidance entitled ''Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 1–800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1071) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the guidance ''Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturer's addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 1–800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for

general information, or arrow down for specific topics.

IV. Comments

Interested persons may, at any time, submit to the contact person (named above) written comments regarding this guidance. Such comments will be considered when determining whether to amend the current guidance.

Dated: August 5, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–251]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS.

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, is publishing the following summary of proposed collections for public comment. 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. Due to an unanticipated event and the fact that this collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320, we are requesting an emergency review.

With the creation of the Medicare+Choice program, as required by the Balanced Budget Act of 1997 (P.L. 105–33), Medicare beneficiaries' health care options were expanded to include coordinated care plans such as Health Maintenance Organizations, Preferred Provider Organizations, Provider sponsored Organizations, as well as Private Fee for Service Plans and Medical Savings Accounts. While the new options bring more flexibility for health care decisions for people with Medicare, they also necessitate the need for a carefully planned, extensive education campaign to assure that Medicare Beneficiaries have understanding of how Medicare offers more health plan choices and how to use HCFA-developed information tools that will be available through an annual publication and the World Wide Web.

The purpose of this submission is to request approval of the Medicare & You bounce back survey form that will be used to collect information from Internet users accessing the Medicare & You, Medicare+Choice Handbook, on the Medicare.gov Web site. This web-based survey will provide critical feedback from our agents, partners, regional offices, congressional offices, and beneficiaries who use the Medicare & You, Medicare+Choice Handbook. The information will be used by HCFA to identify parts of Medicare & You that need to be revised to further enhance HCFA's, Medicare+Choice information strategies and related tools.

HCFA is requesting OMB review and approval of this collection within 6 working days of publication of this notice in the **Federal Register**, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by 5 working days of the publication of this notice. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Request: New Collection.

Title of Information Collection: Medicare & You Bounce Back Survey Form.

Form Number: HCFA–R–251 (OMB approval #: 0938–NEW).

Use: The primary purpose of the bounce back form is to provide HCFA feedback from users of the Medicare+Choice handbook. The information collected through the bounce back form will be used in conjunction with other information collected in the States piloting Medicare & You to make revisions for future publications of the Medicare & You, Medicare+Choice handbook.

Frequency: On occasion.

Affected Public: Individuals or Households, Businesses or other For-profit.

Number of Respondents: 9,855.

Total Annual Responses: 9,855.

Total Annual Hours Requested: 986.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below within 5 working days of the publication of this notice in the **Federal Register**:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–20, 7500 Security Boulevard, Baltimore, MD 21244–1850. Fax Number: (410) 786–0262 Attn: John Rudolph HCFA–R–251 and, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167 Attn: Allison Herron Eydt, HCFA Desk Officer.

Dated: August 6, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

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