clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by April 21, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Irradiation in the Production, Processing, and Handling of Food (21 CFR Part 179)—(OMB Control Number 0910–0186—Reinstatement)

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation as a food additive. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179).

Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.).

Section 179.26(c) requires that food processors label retail packages of irradiated foods with an FDA prescribed logo and statement, ''Treated with radiation'' or ''Treated by irradiation.'' To ensure safe use of radiation sources, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation (§ 179.21(b)(1)(i)) and the maximum energy of radiation emitted by x-ray tube sources (§ 179.21(b)(1)(ii)). Section 179.21(b)(2) requires that the label or accompanying labeling bear adequate directions for installation and use (§ 179.21(b)(2)(i)), a statement that no food shall be exposed to radiation sources so as to receive an absorbed dose of x-radiation in excess of 10 grays (§ 179.21(b)(2)(ii)) or an absorbed dose of certain radioisotopes[1] in excess of 2 milligrays (§ 179.21(b)(2)(iii)).

The records required by § 179.25(e) are used by FDA inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. The agency cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
179.25(e)	3	120	360	1	360

There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of firms who process food using irradiation is extremely limited. FDA estimates that there is a single irradiation plant whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Two other facilities also irradiate small quantities of food (mainly spices). FDA estimates that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on: (1) Facility devoting 100 percent of its business (or 300 hours for recordkeeping annually) to food irradiation; (2) facilities devoting 10 percent of their business or 60 hours (2 x 30 hours) for recordkeeping annually, to food irradiation or (300 + 60)/3 = 120 x 3 firms x 1 hour = 360 hours annually.

No burden has been estimated for the labeling requirements in § 179.21(b)(1) and (b)(2)(i) because it is a usual and customary business practice for manufacturers of food processing equipment to label (identify) their products for use by their customers. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. In addition, no burden has been estimated for §§ 179.21(b)(2)(ii) and (b)(2)(iii) and 179.26(c) because FDA provides the exact wording and logo that is to be used on the label. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: March 13, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–7131 Filed 3–20–97; 8:45 am]

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[1] The isotopes identified by the regulation are americium-241, cesium-137, cobalt-60, iodine-125, krypton-85, radium-226, and strontium-90.

[Docket No. 97D–0099]

Draft Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products; 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, ''Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products.'' The draft guidance considers the quality and quantity of data that may be adequate to add a new use to the prescribing information for a product used in the treatment of cancer. The draft guidance is part of the agency's ''New Use Initiative—Evidence for Primary and Supplemental Approvals,'' which is exploring ways to expedite the development of new and supplemental uses for drug and biological products. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance that discusses what clinical evidence of efficacy should be provided in new drug and biological product license applications as well as in supplemental applications. The agency is seeking public comment on the draft guidance.

DATES: Written comments on the draft guidance by May 20, 1997. General comments on agency guidance documents may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist the offices in processing your requests. The draft guidance also may be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by facsimile by calling the FAX Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert J. Delap, Center for Drug Evaluation and Research (HFD–150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2473.

SUPPLEMENTARY INFORMATION:

I. Background

When drugs approved for one use prove safe and effective for treating other conditions, information on the new use should be added to the product labeling as soon as possible. FDA has launched the ''New Use Initiative—Evidence for Primary and Supplemental Approvals'' to explore ways the agency can improve the supplemental application process. FDA believes it can expedite the development of new and supplemental uses of drug and biological products by doing the following: (1) Clarifying what evidence should be provided in primary as well as supplemental applications and (2) working with industry to reduce barriers to submitting applications for new uses for their products.

Some of the information submitted in a supplemental application may be available from the primary application. As a result, the agency decided that its first step would be to clarify what information sponsors should provide in applications in general. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products,'' The draft guidance addresses the information that should be provided in new drug and biological product license applications as well as supplemental applications.

The draft guidance entitled ''Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products'' focuses on the particular information to be provided when submitting an application for the approval of a supplemental new use for a drug product to treat cancer. Cancer treatments often yield potential new uses for already marketed drugs.

Although this draft guidance does not create or confer any rights on any person, and does not operate to bind FDA in any way, it does represent the agency's current thinking on new cancer treatment uses for marketed drug and biological products.

II. Request for Comments

Interested parties may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the draft guidance also is available via Internet using the World Wide Web (WWW) (connect to the CDER home page at attp://www.fda.gov/cder and go to the ''Regulatory Guidance'' section, or to the CBER home page at http://www.fda.gov/cber/cberfp.html).

Dated: March 14, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–7132 Filed 3–20–97; 8:45 am]

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[Docket No. 97D–0100]

Draft Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products; 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, ''Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products.'' The purpose of the draft guidance is to clarify what clinical evidence of effectiveness should be provided in new drug applications, biological product license applications, and supplemental applications. The draft guidance is part of the agency's ''New Use Initiative—Evidence for Primary and Supplemental Approvals,'' which is exploring ways to expedite the development of new and supplemental uses for drug and biological products. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance that discusses the quality and quantity of data that may be adequate to add a new use to the prescribing information for a product used in the treatment of cancer. The agency is seeking public comment on the draft guidance.

DATES: Written comments on the draft guidance by May 20, 1997. General comments on agency guidance documents may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: