Dated: March 17, 1997.

Bob Williams,

Commissioner Administration on Developmental Disabilities.

[FR Doc. 97–7212 Filed 3–20–97; 8:45 am]

BILLING CODE 4184–01–P

Food and Drug Administration

[Docket No. 97N–0098]

Agency Information Collection Activities: Proposed Collection; Comment Request; Extension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate.''

DATES: Submit written comments on the collection of information by May 20, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Interstate Shellfish Dealers Certificate—(OMB Control Number 0910–0021)—Extension

Under 42 U.S.C. 243, FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP). The NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors. Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate.'' FDA uses this information to publish the ''Interstate Certified Shellfish Shippers List,'' a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, the NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.

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

ESTIMATED ANNUAL REPORTING BURDEN

Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3038	33	70	2,310	.10	231

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

This estimate is based on the numbers of certificates received in 1996.

Dated: March 13, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–7137 Filed 3–20–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97N–0092]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reinstatement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and

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]

BILLING CODE 4160–01–F

[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.