Matters To Be Discussed: The agenda will focus on:

1. NCID Update.
2. Minority and Women's Health.
3. Global Emerging Infectious Diseases.
4. Current Scientific Issues.
5. Workgroup Sessions: Emerging Infectious Disease FY 1997 and FY 1998 Planning:

a. Surveillance and Response Capacity
b. Research
c. Prevention and Control
d. Laboratory Infrastructure

6. Workgroup Reports.
7. Recommendations.

Other agenda items include announcements/introductions; follow-up on actions recommended by the Board (May 1996); and consideration of future directions, goals, and recommendations.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Contact Person for More Information: Diane S. Holley, Office of the Director, NCID, CDC, Mailstop C–20, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–0078.

Dated: October 25, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–28498 Filed 11–5–96; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96N–0403]

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, 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 the recordkeeping and labeling requirements for food irradiation processors.

DATES: Submit written comments on the collection of information by January 6, 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: Kim A. Sanders, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1473.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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.

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

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the act), food irradiation is subject to regulation as a food additive (21 U.S.C. 321(s) and 348). 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 assure 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 source 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:

TABLE 1.—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.

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: October 30, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–28581 Filed 11–5–96; 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. 96D–0390]

Exports: Certificates and Other Assurance that Products Meet FDA Requirements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised Compliance Policy Guide (CPG) 7150.01 entitled ''Certification for Exports.'' Firms exporting products from the United States are often asked by foreign customers or foreign governments to supply a certification relating to products subject to the Federal Food, Drug, and Cosmetic Act (the act) and other acts FDA administers. FDA has historically issued a number of different types of certificates, e.g., Certificates of Free Sale, Certificates for Export, Certificates to Foreign Governments, and the European Union (EU) Health Certificate for Fishery Products. Therefore, FDA has revised CPG 7150.01 to provide guidance on the preparation of certificates, including model forms, and to clarify that it is the responsibility of the certificate requester to provide certain information that will be used by FDA to determine whether a certificate may be issued. The revised guidance is intended to improve agency uniformity and consistency in providing export certifications for FDA-regulated products.

DATES: Effective November 6, 1996. Written comments by February 4, 1997.

ADDRESSES: Send written requests for single copies of CPG 7150.01 ''Certification for Exports'' (CPG 7150.01) to the Director, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send a self-addressed adhesive label to assist that office in processing your requests. Submit written comments on revised CPG 7150.01 to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of revised CPG 7150.01 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: Steven M. Solomon, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0423.

SUPPLEMENTARY INFORMATION: Under the FDA Export Reform and Enhancement Act of 1996, FDA is required to issue certificates for the export of drugs and biologics, animal drugs, and devices that meet the applicable requirements of the act within 20 days of receipt of a request for such a certificate. A fee of up to $175 may be charged for each certificate issued. While FDA is not