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

required to issue certificates for foods, feed additives, nonmedicated feeds, pet foods, and cosmetics, the agency intends to continue to provide this service. In addition to issuing export certificates for products that are approved, licensed, or otherwise in compliance with the applicable requirements of the act, FDA will issue export certificates for products that meet the requirements for export of section 801(e) or 802 of the act (21 U.S.C. 381(e) or 382) but may not otherwise be marketed, sold, offered for sale, or distributed in interstate commerce.

Revised CPG 7150.01 ''Certification for Exports'' describes current agency views on issuing certificates requested by firms to facilitate the export of FDA-regulated products to other countries. While the agency recognizes the current importance of fulfilling requests for export certificates, FDA's long-term goal is to reduce or eliminate export certificates by finding other means to satisfy other countries' needs for reassurance about imported products. The new CPG replaces CPG 7150.01, entitled ''Certificates for Export'' that was issued in 1994.

Although this CPG does not create or confer any rights or benefits for or on any person and does not operated to bind FDA or industry, it does represent the agency's current thinking on issuing export certificates.

Dated: October 31, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–28528 Filed 11–5–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0383]

Export Certificates; FDA Export Reform and Enhancement Act of 1996; Certification Fees for Drugs, Animal Drugs, and Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fees for issuing export certificates. The FDA Export Reform and Enhancement Act of 1996 provides that any person who exports a drug, animal drug, or device may request FDA to certify in writing that the exported drug, animal drug, or device meets certain specified requirements. It further provides that FDA shall issue such a certification within 20 days of the receipt of a request for such certification, and that FDA may charge up to $175 for each certification that is issued within the 20 days. This notice describes the fee schedule for export certifications, the costs that form the basis for those fees, and the billing and collection processes. The agency requests comments on the fee schedule and its effects on small business.

DATES: The fees described herein for export certificates for drugs, animals drugs, and devices became effective October 1, 1996. Written comments should be submitted by February 4, 1997.

ADDRESSES: 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: Lance S. Siegall, Office of Financial Management, Accounting Reports and Analysis Branch (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1768.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Export Reform and Enhancement Act of 1996 became law on April 26, 1996 (Pub. L. 104–134, amended by Pub. L. 104–180, August 6, 1996). The principal purpose of the new law is to expedite the export of FDA-regulated products (both approved and unapproved) through amendments to sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e) and 382). The new law adds a new subsection 801(e)(4) to the act that provides that any person who exports a drug, animal drug, or device may request FDA to certify in writing that the exported drug, animal drug, or device meets the requirements of sections 801(e)(1) or 802 of the act, or other applicable requirements of the act. Upon a showing that the product meets the applicable requirements, the new law further provides that FDA shall issue such a certification within 20 days of the receipt of a request for such certification, and that FDA may charge up to $175 for each such certification that is issued within the 20 day period.

Export certificates are issued for: Drugs, biologics, animal drugs, and medical devices by FDA's: Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM), and the Center for Devices and Radiological Health (CDRH), respectively. Although FDA's Center for Food Safety and Applied Nutrition (CFSAN) issues export certificates for food products and cosmetics, and CVM issues export certificates for feed additives, nonmedicated feeds, and pet foods, the export certificates for these products are not covered by the new law.

II. Agency Costs and Fees to be Assessed for Export Certificates

FDA has determined the costs to the agency for preparing export certificates based upon the following:

(1) Direct personnel for the research, review, tracking, writing, and assembly;

(2) Purchase of equipment and supplies used for tracking, processing, printing, and packaging. Recovery of the cost of the equipment is calculated over its useful life;

(3) Billing and collection of fees; and

(4) Overhead and administrative support.

These costs vary with the Center issuing the certificates, largely because of differences in the types of products, and the procedures used in evaluating the compliance status of the manufacturing site(s). As mentioned above, the agency may charge up to $175 for each certificate. Certificates for some classes of products cost the agency more than $175 to prepare. Subsequent certificates issued for the same products in response to the same request generally cost the agency less than $175. The fee for the second certificate for the same product(s) issued in response to the same request reflects the agency cost for preparing the second certificate plus the difference (if any) between the agency cost for preparing the first certificate and the $175 maximum fee. The fee for all subsequent certificates for the same product(s) issued in response to the same request reflects agency costs for preparing those certificates only. The agency has developed the following fee structure, which reflects agency costs for the following Centers:

(1) CBER: $175 for the first certificate; $175 for the second certificate for the same product(s) issued in response to the same request; $85 for each subsequent certificate for the same product(s) issued in response to the same request.

(2) CVM: $175 for the first certificate; $155 for the second certificate for the same product(s) issued in response to the same request; $70 for each subsequent certificate for the same product(s) issued in response to the same request.

(3) CDER: $175 for the first certificate; $90 for the second certificate with attachments for the same product(s) issued in response to the same request; $40 for any subsequent certificates with attachments for the same product(s) issued in response to the same request; $15 for second and subsequent