when appropriate, and other forms of information technology.

Importer's Entry Notice (OMB Control Number 0910–0046)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) charges FDA with the following responsibilities: (1) Ensuring that foreign-origin FDA-regulated foods, drugs, cosmetics, medical devices, and radiological health products offered for import into the United States meet the same requirements of the act as do domestic products; and (2) preventing shipments from entering the country if they are not in compliance.

The information collected by FDA consists of the following: (1) Product code, an alpha-numeric series of characters that identifies each product FDA regulates; (2) FDA country of origin, the country where the FDA-registered or FDA-responsible firm is located; (3) FDA manufacturer, the party who manufactured, grew, assembled, or otherwise processed the goods (if more than one, the last party who substantially transformed the product); (4) shipper, the party responsible for packing, consolidating, or arranging the shipment of the goods to their final destination; (5) quantity and value of the shipment; and (6) if appropriate, affirmation of compliance, a code that conveys specific FDA information, such as registration number, foreign government certification, etc. This information is collected electronically by the entry filer via the U.S. Customs Service's Automated Commercial System at the same time he/she files an entry for import with the U.S. Customs Service. FDA uses the information to make admissibility decisions about FDA-regulated products offered for import into the United States.

The annual reporting burden is derived from the basic processes and procedures used in fiscal year (FY) 1995. The total number of entries submitted to the automated system in FY 1999 was 5,077,493. The total number of entries less the disclaimed entries will represent the total FDA products entered into the automated system. A total of 51 percent of all entries entered into the automated system were entries dealing with FDA-regulated products. The number of respondents is a count of filers who submit entry data for foreign-origin FDA-regulated products. The estimated reporting burden is based on information obtained by FDA contacting some potential respondents. Disclaimed entries are not FDA commodities.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,886	652	2,533,355	.14	354,669

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

Dated: March 15, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–7010 Filed 3–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0928]

Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Samples and Protocols

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 the information collection provisions relating to the regulations which state that protocols for samples of biological products must be submitted to the agency.

DATES: Submit written comments on the collection of information by May 22, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 set forth in this document.

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.

Request for Samples and Protocols (OMB Control No. 0910–0206)—Extension

Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity, and potency of biological products and to ensure that licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), FDA may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot along with the protocols showing the results of applicable tests prior to marketing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols for specific licensed biological products as follows: Sections 640.101(f) (21 CFR 640.101(f)) (Immune Globulin (Human)), 660.6 (21 CFR 660.6) (Antibody to Hepatitis B Surface Antigen), 660.36 (21 CFR 660.36) (Reagent Red Blood Cells), and 660.46 (21 CFR 660.46) (Hepatitis B Surface Antigen).

Section 640.101(f)(2) requires for each lot of Immune Globulin (Human) product, the submission of all protocols relating to the history of the product and all results of all tests prescribed in the additional standards for the product.

Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by the Center for Biologics Evaluation and Research (CBER). After official release is no longer required, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires a protocol containing information including, but not limited to, manufacturing records, test records, and test results. Section 660.36(b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to FDA at the time of initial distribution of each lot.

Section 660.46(a) provides requirements for the frequency of submission of samples from each lot of Hepatitis B surface antigen product, and § 660.46(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary.

Samples and protocols are required by FDA to help ensure the safety, purity, or potency of the product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (e.g., Albumin, Plasma Protein Fraction, and specified biotechnology and specified synthetic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of any licensed biological product. Respondents to the collection of information under §§ 640.101(f)(2), 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products, including submissions for lot release, surveillance, licensing, or export. There are an estimated 350 manufacturers of licensed biological products, however, based on information obtained from FDA's data base system, approximately 100 manufacturers submitted samples and protocols in 1998, under the regulations cited previously. FDA estimates that approximately 86 manufacturers submitted protocols under § 610.2 and 14 manufacturers submitted protocols under the regulations for the specific products. FDA had previously estimated 80, instead of 90, manufacturers would submit samples and protocols annually under all the regulations cited previously to account for biotechnology firms that are exempt from lot release requirements. Because biotechnology firms may still be required to submit samples and protocols for purposes other than lot release, as explained previously, the number of respondents for § 610.2 in this estimate includes them. The slight increase in the total estimated number of respondents (100) is due to a normal variation in annual submissions.

The total annual responses are based on FDA's final actions completed in fiscal year 1998, which totaled 7,221, for the various submission requirements of samples and protocols for biological products. The rate of final actions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the hours per response are based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the protocol than under § 610.2.

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

TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.2	86	82.72	7,114	3	21,342
640.101(f)(2)	5	4.40	22	5	110
660.6(b)	6	11.33	68	5	340
660.36(a)(2) and (b)	1	1	1	6	6
660.46(b)	2	8	16	5	80
Total					21,878

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

Dated: March 15, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–7012 Filed 3–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–5325]

Agency Information Collection Activities; Submission for OMB Review; Irradiation in the Production, Processing, and Handling of Food

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, 2000.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 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—21CFR Part 179 (OMB Control Number 0910–0186—Extension)

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).

To assure safe use of radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum energy of radiation emitted by X-ray tube sources. Section 179.21(b)(2)(i) requires that the label or accompanying labeling bear adequate directions for installation and use.

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.).

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.

In the **Federal Register** of December 29, 1999 (64 FR 73054), the agency requested comments on the proposed collections of information (hereinafter referred to as the 60-day notice). No significant comments were received.

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

TABLE1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

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

[1] 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 firms 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. Although recent FDA rulemaking has authorized the irradiation of red meat, the United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) has yet to issue a rule regarding meat irradiation. Actual implementation of meat irradiation cannot take place until USDA/FSIS final regulations are in place, which may not take place until later this fiscal year. At this time, FDA has no basis for estimating the extent of changes in the food irradiation business