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 May 17, 2012 (77 FR 29352), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received outside the scope of the four collection of information topics solicited by the notice.

Description of respondents: Respondents are businesses engaged in the irradiation of food.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
179.25(e), Large Processors	3	300	900	1	900
179.25(e), Small Processors	4	30	120	1	120
Total					1,020

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

FDA bases its estimate of burden for the recordkeeping provisions of § 179.25(e) on the Agency's experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. FDA estimates that there are 3 irradiation plants whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. 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 3 facilities devoting 100 percent of their business to food irradiation (3×300 hours = 900 hours for recordkeeping annually), and 4 facilities devoting 10 percent of their business to food irradiation (4×30 hours = 120 hours for recordkeeping annually).

No burden has been estimated for the labeling requirements in §§ 179.21(b)(1), 179.21(b)(2), and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. 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: July 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18234 Filed 7–25–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0280]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 27, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0396. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

Financial Disclosure by Clinical Investigators—(OMB Control Number 0910–0396)—Extension

Respondents to this collection are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. Respondents are also clinical investigators who provide financial information to the sponsors of marketing applications.

Under § 54.4(a) (21 CFR 54.4(a)), applicants submitting an application that relies on clinical studies must submit a complete list of clinical investigators who participated in a covered clinical study, and must either certify to the absence of certain financial arrangements with clinical investigators (Form FDA 3454) or, under § 54.4(a)(3), disclose to FDA the nature of those arrangements and the steps taken by the applicant or sponsor to minimize the potential for bias (Form FDA 3455).

Under § 54.6, the sponsors of covered studies must maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for a time period of 2 years after the date of approval of the applications. Sponsors of covered studies maintain many records with

regard to clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates than an average of 15 minutes will be required for each recordkeeper to add this record to the clinical investigators' file.

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that it will take clinical investigators 15 minutes to submit such records to the sponsor.

Subsequent to publication of the 60-day notice, FDA reestimated the information collection. Upon additional inspection of the data, FDA has updated the estimated recordkeeping burden hours to more accurately reflect the burden.

In the **Federal Register** of March 28, 2012 (77 FR 18826), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Certification—54.4(a)(1) and (a)(2)—Form FDA 3454	902	1	902	1	902
Disclosure—54.4(a)(3)—Form FDA 3455	90	1	90	5	450
Total					1,352

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping—54.6	902	1	902	0.25	226

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Clinical Investigators—54.4(b)	10,554	1	10,554	0.17	1,794

Dated: July 16, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18235 Filed 7–25–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0748]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Drug User Fee Cover Sheet; Form FDA 3794

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments concerning collection of information using Form FDA 3794 entitled ''Generic Drug User Fee Cover Sheet.''

DATES: Submit either electronic or written comments on the collection of information by September 24, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov*.

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 before submitting the collection to OMB for approval. To