TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section II; Human Food	3942a	37,134	.5	18,567	.5 (30 minutes)	9,284
Section III; Animal Food	3942b	1,120	.5	560	.5 (30 minutes)	280
Total						9,564

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

Consistent with the estimates found in our Preventive Controls for Human Food Rule, we estimate that approximately 37,134 human food facilities will each spend approximately 30 minutes (0.5 hour) reporting their status as a qualified facility to FDA every 2 years. Thus, dividing this figure by two to determine the annual burden, we estimate there will be 18,567 responses and 9,284 burden hours associated with this information collection element.

Similarly, and consistent with the estimates found in our Preventive Controls for Animal Food Rule, we estimate that approximately 1,120 animal food facilities will each spend approximately 30 minutes (0.5 hour) reporting their status as a qualified facility to FDA every 2 years. Thus, dividing this figure by two to determine the annual burden, we estimate there will be 560 responses and 280 burden hours associated with this information collection element.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 117 have been approved under OMB control number 0910–0751. The collections of information in 21 CFR part 507 have been approved under OMB control number 0910–0789.

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12615 Filed 6–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0073]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 July 12, 2018.

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 0910–0186. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@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.

Irradiation in the Production, Processing, and Handling of Food

OMB Control Number 0910–0186—Extension

This information collection supports FDA regulations. Specifically, under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the FD&C Act. 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 ensure safe use of a 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 (or minimum and maximum) energy of the emitted radiation. Section 179.21(b)(2) requires that the label or accompanying labeling bear adequate directions for installation and use and a statement supplied by FDA that indicates maximum dose of radiation allowed. Section 179.26(c) requires that the label or accompanying labeling bear a logo and a radiation disclosure statement. 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. We 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 January 26, 2018, (83 FR 3734), 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 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); records for large processors	4	300	1,200	1	1,200
179.25(e); records for small processors	4	30	120	1	120
Total					1,320

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

Upon review of the information collection we have retained the currently approved burden estimate. FDA's estimate of the recordkeeping burden under § 179.25(e) is based on experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. We estimate that there are four 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. We estimate 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 four facilities devoting 100 percent of their business to food irradiation (4 × 300 hours = 1,200 hours for recordkeeping annually), and four 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 disclosures are 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 subject to review by the OMB under the Paperwork Reduction Act of 1995.

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12614 Filed 6–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–D–0155]

General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry (GFI) #3 entitled ''General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals.'' This guidance describes the type of information that the FDA's Center for Veterinary Medicine (CVM) recommends sponsors provide to address the human food safety of new animal drugs used in food-producing animals. The human food safety evaluation of new animal drugs used in food-producing animals helps ensure that food derived from treated animals is safe for human consumption. CVM developed this guidance to inform sponsors of the scientific data and/or information that may provide an acceptable basis to determine that the residue of a new animal drug in or on food, when consumed, presents a reasonable certainty of no harm to humans.

DATES: The announcement of the guidance is published in the **Federal Register** on June 12, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2005–D–0155 for ''General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly