TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
202.1(j)(1)(iii); assuring that adverse information be publicized	1	1	1	12	12
202.1(j)(4); voluntary submission of ad to FDA	7	2.57	18	20	360
CVM Regulated Products:					
202.1(e)(6); waiver request	1	1	1	12	12
202.1(j)(1); submission of advertisement	1	1	1	2	2
202.1(j)(1)(iii); assuring that adverse information be publicized	1	1	1	12	12
202.1(j)(4); voluntary submission of ad to FDA	7	1	7	20	140
Total			143		2,758

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

Our estimate of burden we attribute to the reporting provisions in part 202 is based on our experience with the collection and a review of Agency data.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1] [2]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Burden per disclosure	Total hours
202.1; ad prepared in accordance with part 202	670	111.08	74,425	400	29,770,000
202.1(j)(1); info. included re. fatalities or serious damage	1	1	1	40	40
Total			74,426		29,770,040

[1] There are no capital costs or operating and maintenance costs associated with this collection.
[2] Numbers rounded to the nearest one/one-hundredth.

Under § 202.1, advertisements for human and animal prescription drug and biological products must comply with the standards described in that section. Under § 202.1(j)(1), if information that the use of a prescription drug may cause fatalities or serious damage has not been widely publicized in the medical literature, a sponsor must include such information in the advertisements for that drug. Based on a review of Agency data we estimate an average of 29,770,040 hours is incurred annually by respondents in complying with third-party disclosure requirements for prescription drug advertising. We assume a placeholder of 1 for disclosures under § 202.1(j)(1).

TABLE 3—ESTIMATED ANNUAL DISCLOSURE BURDEN DISCUSSED IN AGENCY GUIDANCE

Information collection recommendations	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
Product name placement, size, and prominence in promotional labeling and advertisements' disclosures	715	190.3	136,069	3	408,207

The placement, size, prominence, and frequency of the proprietary and established names for human prescription drugs, including prescription biological products, and animal prescription drugs are specified in labeling and advertising regulations (§§ 201.10(g) and (h); 202.1(b), (c), and (d)). Based on Agency data, we estimate that, for human and animal prescription drugs and prescription biological products, an average of 715 firms disseminate approximately 136,069 advertisements and promotional pieces each year. We assume that the burden associated with complying with the regulatory requirements discussed in the guidance would be approximately 3 hours per response.

We have adjusted our estimate upward by 11,705,225 hours annually to reflect increases in prescription drug advertisements and associated disclosures.

Dated: April 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–08948 Filed 4–28–21; 8:45 am]

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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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by June 1, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0186. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 used to treat food, § 179.21(b)(1) (21 CFR 179.21(b)(1)) requires that the label of the radiation 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 us that indicates maximum dose of radiation allowed. Section 179.26(c) (21 CFR 179.26(c)) requires that the label or accompanying labeling of foods treated by a source of radiation bear a logo and a radiation disclosure statement.

Section 179.25(e) (21 CFR 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 our 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.

Description of Respondents: Respondents to the information collection are businesses engaged in the irradiation of food.

In the **Federal Register** of October 16, 2020 (85 FR 65825), we published a 60-day notice requesting public comment on the proposed collection of information. Although three comments were received, none pertained to the information collection topics solicited in the notice or suggested a change to our burden estimate.

We estimate 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	4	300	1,200	1	1,200
179.25(e), 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.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Our estimate of the recordkeeping burden under § 179.25(e) is based on our 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, and four facilities devoting 10 percent of their business to food irradiation.

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 OMB under the PRA.

Dated: April 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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