

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 us 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 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 January 23, 2024 (89 FR 4311), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment related to the PRA was received which suggested that FDA could enhance and improve the information received in this collection of information by clarifying reporting requirements, detailing consistent guidelines, conducting training and educational programs to increase understanding, and integrating technology into the process. The

comment also indicated that regular audits and checks should be instituted, and the implementation of these suggestions will increase the quality of the information being collected.

FDA strives to protect the public health and safety in irradiated food and packaging. FDA's website at <https://www.fda.gov/food/food-ingredients-packaging/irradiation-food-packaging> provides a discussion of FDA's regulation of irradiated food as well as information about the history, science, and regulations of irradiated food and packaging. In addition, FDA offers educational webinars, such as the joint CFSAN/JFSAN webinar on Food Packaging and Irradiation. This webinar can be found on YouTube at https://www.youtube.com/watch?v=X3rYqwHx_KU. This webinar provides some clarification on food processing and handling of irradiated food. FDA also conducts inspections on an as-needed basis to check on the accuracy of the records being maintained by food processors and to ensure the safety of irradiated food and packaging.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

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: June 4, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-0008]

Advisory Committee; Arthritis Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Arthritis Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Arthritis Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the April 5, 2026, expiration date.

DATES: Authority for the Arthritis Advisory Committee will expire on April 5, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Jessica Seo, Center for Drug Evaluation Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, AAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Arthritis Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases, and makes appropriate recommendations to the Commissioner.

Pursuant to its Charter, the Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of arthritis, rheumatology, orthopedics, epidemiology or statistics, analgesics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives, or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of

other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/human-drug-advisory-committees/arthritis-advisory-committee> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 et seq). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: June 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0335]

Advisory Committee; Obstetrics, Reproductive and Urologic Drugs Advisory; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Obstetrics, Reproductive and Urologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Obstetrics, Reproductive and Urologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the March 23, 2026, expiration date.

DATES: Authority for the Obstetrics, Reproductive and Urologic Drugs Advisory Committee will expire on March 23, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-7973, email: ORUDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Obstetrics, Reproductive and Urologic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of obstetrics, gynecology, urology, and related specialties, and makes