self-nominated or nominated by an organization to serve as a nonvoting industry representative. This position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any small business tobacco manufacturing industry organization interested in participating in the selection of appropriate nonvoting members to represent industry interests must send a letter stating that interest to the FDA by September 11, 2023, (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by September 11, 2023.

ADDRESSES: All statements of interest from small business tobacco manufacturing industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent to CAPT Serina Hunter-Thomas (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm.* Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Office of Science, Center for Tobacco Products, Food and Drug Administration, Center for Tobacco Products Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373 (choose Option 5), or by email: *TPSAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add nonvoting industry representative(s) to the following advisory committee:

I. Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of FDA (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

The Committee includes three nonvoting members who represent industry interests. These members include one representative representing the interests of the tobacco manufacturing industry, one representative representing the interests of tobacco growers, and one representative representing the interests of the small business tobacco manufacturing industry, which may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee.

With this notice, nominations are sought for the following positions: A pool of individuals, with varying areas of expertise, to represent the interests of the small business tobacco manufacturing industry on a rotating, sequential basis.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women, and men, members of all racial and ethnic groups and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17149 Filed 8–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0583]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Radioactive Drug Research Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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: Submit written comments (including recommendations) on the collection of information by September 11, 2023.

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 0910–0053. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three

White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Radioactive Drug Research Committees

OMB Control Number 0910–0053—Extension

This information collection request supports the implementation of statutory and regulatory requirements and associated Agency forms. Sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371) establish provisions under which FDA issues regulations governing the use of radioactive drugs for basic scientific research. Specifically, § 361.1 (21 CFR 361.1) sets forth specific regulations about establishing and composing radioactive drug research committees (RDRCs) and their role in approving and monitoring basic research studies using radiopharmaceuticals, including reporting, recordkeeping, and labeling requirements. No basic research study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA-approved RDRC (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial for safety or efficacy. The types of basic research permitted are specified in the regulations and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

To assist respondents with the applicable reporting requirements, we developed Form FDA 2914 entitled, ''Report on Research Use of Radioactive Drugs: Membership Summary,'' available at *https://www.fda.gov/media/73820/download;* and Form FDA 2915, entitled, ''Report on Research Use of Radioactive Drugs: Study Summary,'' available at *https://www.fda.gov/media/71805/download.*

We also developed the guidance document entitled, ''Radioactive Drug Research Committee: Human Research Without An Investigational New Drug Application'' (August 2010), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radioactive-drug-research-committee-human-research-without-investigational-new-drug-application,* which provides information to help determine whether research studies may be conducted under an FDA-approved RDRC, or whether research studies must be conducted under an investigational new drug application (IND). It also offers answers to frequently asked questions on conducting research with radioactive drugs, and provides information on the membership, functions, and reporting requirements of an RDRC approved by FDA. All Agency guidance documents are issued consistent with our good guidance practice regulations at 21 CFR 10.115.

Types of research studies not permitted under the regulations are also specified and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (*i.e.,* to carry out a clinical trial for safety or efficacy). These studies require filing of an IND under 21 CFR part 312, and the associated information collections, are covered in OMB control number 0910–0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks. Respondents to this information collection are the chairperson or chairpersons of each individual RDRC, investigators, and participants in the studies.

In the **Federal Register** of March 16, 2023 (88 FR 16272), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; FDA form or activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 361.1(c)(3) reports and (c)(4) approval; Form FDA 2914 (Membership Summary).	56	1	56	1	56
§ 361.1(c)(3) reports; Form FDA 2915 (Study Summary)	37	10	370	3	1,110
§ 361.1(d)(8); adverse events	10	1	10	0.5 (30 mins)	5
Total					1,171

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; and activity	Number of recordkeepers	Number of records per recordkeepers	Total annual records	Average burden per recordkeeping	Total Hours
§ 361.1(c)(2); RDRC maintains meeting minutes involving use in human research subjects. § 361.1(d)(5); RDRC obtains consent of human research subjects.	56	10.61	594	4.239	2,518
Total					2,518

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

The burden attributed to recordkeeping activities is assumed to be distributed among the individual elements and averaged among respondents. In the burden estimate, we assume an average burden per record of 10 hours for the RDRC respondents to maintain meeting minutes and 0.75 hours (45 minutes) for a subset of the respondents (37 RDRCs) to obtain consent of human research subjects.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Our estimated burden for the information collection reflects an overall decrease of 703 hours and a corresponding decrease of 158 responses. We attribute this adjustment to a decrease in the average burden per response, from 3.5 hours to 3 hours per response, associated with the public reporting burden for Form FDA 2915. The decrease is based on our program experience and matches the burden hours reflected on the form. In addition, this adjustment is also attributable to the Agency receiving fewer submissions over the last few years.

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17154 Filed 8–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0918]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling Requirements

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: Submit written comments (including recommendations) on the collection of information by September 11, 2023.

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 0910–0381. 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, 10 a.m.–12 p.m., 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.

Food Labeling Requirements

OMB Control Number 0910–0381—Revision

This information collection supports statutory and regulatory requirements that govern food labeling, and information collection recommendations discussed in associated Agency guidance. Sections 4, 5, and 6 of the Fair Packaging and Labeling Act (FPLA) (15 U.S.C. 1453, 1454, and 1455) and sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e), establish provisions under which a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. Implementing regulations are codified in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105). While regulations in part 101 set forth general food labeling provisions, requirements pertaining to the common or usual name for nonstandardized foods; guidelines for nutritional quality to prescribe the minimum level or range of nutrient composition appropriate for a given class of food; and requirements for foods for special dietary use are found in parts 102, 104, and 105, respectively. The requirements are intended to ensure the safety of food products produced or sold in the United States and enable consumers to be knowledgeable about the foods they purchase and include corresponding information disclosure requirements, along with the reporting and recordkeeping provisions, subject to enforcement by FDA.

We provide information resources regarding food labeling under the FD&C Act and its amendments on our website at *https://www.fda.gov/food/food-labeling-nutrition.* Food labeling is required for most prepared foods, such as breads, cereals, canned and frozen foods, snacks, desserts, drinks, etc. Nutrition labeling for raw produce (fruits and vegetables) and fish is voluntary. We refer to these products as ''conventional'' foods. For detailed information on dietary supplement labeling requirements visit our website at *https://www.fda.gov/food/dietary-supplements.* Nutrition labeling provides information for use by consumers in selecting a nutritious diet. Other information enables consumers to comparison shop. Ingredient information also enables consumers to avoid substances to which they may be sensitive. Petitions or other requests submitted to us provide the basis for us to permit new labeling statements or to grant exemptions from certain labeling requirements. Recordkeeping requirements enable us to monitor the basis upon which certain label statements are made for food products and whether those statements are in compliance with the requirements of the FD&C Act or the FPLA. Requirements include general content and format for the labeling of food packaging, including nutrition and ingredient information. Additional regulations provide for specific nutrient content claims.

The information collection includes Form FDA 3570 entitled, ''Small Business Nutrition Labeling Exemption Notice,'' for use as applicable and available for download from our website at *https://www.fda.gov/food/labeling-nutrition-guidance-documents-regulatory-information/small-business-nutrition-labeling-exemption-notice-model-form.* We have also developed the following guidance documents to assist respondents with various aspects of the information collection:

- ''*Guidance for Industry:* Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' (June 1998). The guidance document is available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-notification-health-claim-or-nutrient-content-claim-based-authoritative-statement.* The guidance document