comments should be identified with the OMB control number 0910–0537. 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.

Bar Code Label Requirement for Human Drug and Biological Products

OMB Control Number 0910–0537—Extension

In the **Federal Register** of February 26, 2004 (69 FR 9120), FDA issued a final rule that requires human drug product and biological product labels to have bar codes. Specifically, the final rule requires bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed under an order and commonly used in healthcare facilities. It also requires machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed under an order and commonly used in healthcare facilities, the bar code must contain the national drug code number for the product. For blood and blood components, the final rule specifies the minimum contents of the label in a format that is machine readable and approved for use by the Director, Center for Biologics Evaluation and Research. We believe that the final rule helps reduce the number of medication errors in hospitals and other healthcare settings by allowing healthcare professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Although most of the information collections created by the final rule have now been incorporated in OMB approved information collections supporting the applicable regulations, respondents to the collection may continue to seek an exemption from the bar code label requirement under § 201.25(d) (21 CFR 201.25(d)). Section 201.25(d) requires submission of a written request for an exemption and describes the information that must be included in such a request. Based on the number of exemption requests we have received previously, we estimate that approximately two exemption requests will be submitted annually and each exemption request will require 24 hours to complete. This results in an annual reporting burden of 48 hours, as reflected in table 1.

In the **Federal Register** of November 1, 2018 (83 FR 54930), we 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	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
21 CFR 201.25(d)	2	1	2	24	48

[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.

Dated: July 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15488 Filed 7–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1265]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling: Nutrition Facts Label and Supplement Facts Label

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 21, 2019.

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 0910–0813. 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.

Food Labeling: The Nutrition Facts Label and Supplement Facts Label—21 CFR 101.9

OMB Control Number 0910–0813—Extension

This information collection supports requirements for the Nutrition Facts and Supplemental Facts labels. Section 403(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(q)) specifies certain nutrients to be declared in nutrition labeling and authorizes the Secretary of Health and Human Services (Secretary) to require other nutrients to be declared if the Secretary determines that a nutrient will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices. The Secretary also has

discretion under section 403(q) of the FD&C Act to remove, by regulation and under certain circumstances, nutrient information that is otherwise explicitly required in food labeling under this section. Accordingly, we issued regulations in § 101.9 (21 CFR 101.9) setting forth how nutrition information is presented to consumers. The regulations also establish standards to define serving size and require that certain products provide additional information within the Nutrition Facts label that conveys that information to consumers.

Specifically, §§ 101.9 and 101.36 list nutrients that are required or permitted to be declared; provide Daily Reference Values and Reference Daily Intake values that are based on current dietary recommendations from consensus reports; provide requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women and establish nutrient reference values specifically for these population subgroups; and provide the format and appearance of the Nutrition Facts label. Section 101.12 (21 CFR 101.12) defines a single-serving container; requires dual-column labeling for certain containers; updates, modifies, and provides several reference amounts customarily consumed (RACCs); provides the label serving size for breath mints; and provides various aspects of the serving size regulations.

The regulations also require that, under certain circumstances, manufacturers make and keep certain records to verify the amount of added sugars when a food product contains both naturally occurring sugars and added sugars, isolated or synthetic non-digestible carbohydrates that do not meet the definition of dietary fiber, different forms of vitamin E, and folate/folic acid declared on the Nutrition Facts or Supplement Facts label, which is the amount in the finished food product.

Firms make and keep certain records necessary to verify the amount of the nutrients in the finished food product. This collection of information does not specify what records are to be used to verify the amounts of these nutrients but does specify the information that the records must contain. The collection requires manufacturers to provide FDA, upon request during an inspection, with the records that contain the required information for each of these nutrients to verify the amount of the nutrient declared on the label. These records may include analyses of nutrient databases, recipes or formulations, information from recipes or formulations, batch records, or any other records that contain the required information to verify the nutrient content in the final product.

Description of Respondents: Respondents to this collection of information are manufacturers of food products sold in the United States. Respondents are from the private sector (for-profit businesses).

In the **Federal Register** of April 19, 2019 (84 FR 16513), we published a 60-day notice requesting public comment on the proposed collection of information. One anonymous comment was received that made specific suggestions on how labeling might be improved, but that supported the overall goals of food labeling and making information available to consumers. The comment made no comments regarding our burden estimate.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of declaration; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Added Sugars; 101.9(c)(6)(iii) [2]	31,283	1	31,283	1	31,283
Dietary Fiber; 101.9(c)(6)(i) [2]	31,283	1	31,283	1	31,283
Soluble Fiber; 101.9(c)(6)(i)(A) [2]	31,283	1	31,283	1	31,283
Insoluble Fiber; 101.9(c)(6)(i)(B) [2]	31,283	1	31,283	1	31,283
Vitamin E; 101.9(c)(8) [3]	31,283	1	31,283	1	31,283
Folate/Folic Acid; 101.9(c)(8) [3]	31,283	1	31,283	1	31,283
New Products	216	1	216	1	216
Total					187,914

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

[2] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for added sugars, dietary fiber, and soluble and insoluble fiber. Manufacturers will only need to keep records for products with both added and naturally occurring sugars, added sugars that undergo fermentation in certain fermented foods, and products with non-digestible carbohydrates (soluble or insoluble) that do and do not meet the definition of dietary fiber.

[3] These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for vitamin E and folate/folic acid. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes.

Based on our experience with food labeling regulations, records that are required to be retained are records that a prudent and responsible manufacturer uses and retains as a normal part of doing business, *e.g.,* analyses of nutrient databases, recipes or formulations, batch records, or other records. Thus, the recordkeeping burden of this collection of information consists of the time required to identify and assemble the records for copying and retention. Based on our previous experience with similar information collections, we estimate the recordkeeping burden to be 1 hour per product as estimated in table 1.

The declarations for added sugars, dietary fiber, soluble fiber, and insoluble fiber are mandatory, and we conservatively estimate all of the roughly 31,283 food manufacturers would incur this recordkeeping burden and the required recordkeeping would be 1 hour per manufacturer. These calculations are reflected in table 1, rows 1 to 4. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes. However, we conservatively estimate that all 31,283 respondents would incur this recordkeeping burden and that the required recordkeeping would be 1 hour per manufacturer. These calculations are reflected in table 1, rows 5 and 6.

We estimate that the number of newly introduced products that are covered under this collection of information is 216. We assume the required recordkeeping is 1 hour per product, for

an annual recurring recordkeeping burden of 216 hours, as reflected in table 1, row 7. Adding the burden from new products to the burden for existing products results in a total of 187,914 annual recordkeeping burden hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Filing of citizen petition regarding a particular isolated or synthetic non-digestible carbohydrate	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Dietary Fiber; 101.9(c)(6)(i)	28	1	28	1	28

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

Manufacturers of food products that contain an isolated or synthetic non-digestible carbohydrate that is not listed in the definition of dietary fiber have the option of submitting a citizen petition to FDA requesting us to amend the definition of ''dietary fiber'' to include the carbohydrate as a listed dietary fiber, by demonstrating the physiological benefits of the isolated or synthetic non-digestible carbohydrate to human health.

We estimate that there are approximately 28 isolated or synthetic non-digestible carbohydrates that do not meet the definition of dietary fiber. Once a citizen petition filed by a manufacturer related to a particular isolated or synthetic non-digestible carbohydrate is granted or denied, or the carbohydrate is the subject of an authorized health claim, and the dietary fiber is listed in the definition of dietary fiber, the use of the dietary fiber as an ingredient in any food product must be included in the total amount of dietary fiber declared in nutrition labeling for such product.

Thus, we estimate that 28 manufacturers would incur burden associated with filing a citizen petition to amend the listing of dietary fiber related to an isolated and synthetic non-digestible carbohydrate that is not currently listed in the definition of dietary fiber and that the required recordkeeping would be 1 hour per manufacturer. This calculation is shown in table 2.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR 101.9	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Nutritional labeling for new products	500	1	500	2	1,000

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

Under §§ 101.9 and 101.12, some manufacturers of retail food products make labeling changes to modify the serving sizes and other nutrition information based on changes to what products may be or are required to be labeled as a single serving, or based on updated, modified, or established RACCs. We estimate that about 500 new products will be affected by these requirements each year and that the associated disclosure burden is 2 hours per product, for an annual burden of 1,000 hours. This information collection reflects adjustments resulting from regulations that have become effective since last OMB review (RIN 0910–AF22). Accordingly, we have lowered our third-party disclosure estimate to reflect that burden associated with changes in labeling resulting from the new requirements has since been realized by respondents. This results in a decrease of 1,149,158 annual disclosures and 2,299,816 burden hours attributable to those labeling changes.

Dated: July 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15523 Filed 7–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Pain and Opioid use in Hemodialysis Patients.

Date: August 6, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites—Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–4721, *ryan.morris@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 16, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–15463 Filed 7–19–19; 8:45 am]

BILLING CODE 4140–01–P