

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.
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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.

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