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

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
101.3, 101.22, parts 102 and 104; statement of identity labeling requirements	25,000	1.03	25,750	0.5 (30 minutes)	12,875
101.4, 101.22, 101.100, parts 102, 104 and 105; ingredient labeling requirements	25,000	1.03	25,750	1	25,750
101.5; requirement to specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its connection with the food product.	25,000	1.03	25,750	0.25 (15 minutes)	6,438
101.9, 101.13(n), 101.14(d)(3), 101.62, and part 104; labeling requirements for disclosure of nutrition information.	25,000	1.03	25,750	4	103,000
101.9(g)(9) and 101.36(f)(2); alternative means of compliance permitted	12	1	12	4	48
101.10; requirements for nutrition labeling of restaurant foods	300,000	1.5	450,000	0.25 (15 minutes)	112,500
101.12(b); RACC for baking powder, baking soda, and pectin	29	2.3	67	1	67
101.12(e); adjustment to the RACC of an aerated food permitted	25	1	25	1	25
101.12(g); requirement to disclose the serving size that is the basis for a claim made for the product if the serving size on which the claim is based differs from the RACC.	5,000	1	5,000	1	5,000
101.13(d)(1) and 101.67; requirements to disclose nutrition information for any food product for which a nutrient content claim is made.	200	1	200	1	200
101.13(j)(2) and (k), 101.54, 101.56, 101.60, 101.61, and 101.62; additional disclosure required if the nutrient content claim compares the level of a nutrient in one food with the level of the same nutrient in another food.	5,000	1	5,000	1	5,000
101.13(q)(5); requirement that restaurants disclose the basis for nutrient content claims made for their food.	300,000	1.5	450,000	0.75 (45 minutes)	337,500
101.14(d)(2); general requirements for disclosure of nutrition information related to health claims for food products.	300,000	1.5	450,000	0.75 (45 minutes)	337,500
101.15; requirements pertaining to prominence of required statements and use of foreign language.	160	10	1,600	8	12,800
101.22(i)(4); supplier certifications for flavors designated as containing no artificial flavors.	25	1	25	1	25
101.30 and 102.33; labeling requirements for fruit or vegetable juice beverages	1,500	5	7,500	1	7,500
101.36; nutrition labeling of dietary supplements	300	40	12,000	4.025	48,300
101.42 and 101.45; nutrition labeling of raw fruits, vegetables, and fish	1,000	1	1,000	0.5 (30 minutes)	500
101.45(c); databases of nutrient values for raw fruits, vegetables, and fish	5	4	20	4	80
101.79(c)(2)(i)(D); disclosure requirements for food labels that contain a folate/neural tube defect health claim.	1,000	1	1,000	0.25 (15 minutes)	250
101.79(c)(2)(iv); disclosure of amount of folate for food labels that contain a folate/neural tube defect health claim.	100	1	100	0.25 (15 minutes)	25
101.100(d); disclosure of agreements that form the basis for exemption from the labeling requirements of section 403(c), (e), (g)–(i), (k), and (q) of the FD&C Act.	1,000	1	1,000	1	1,000
101.7 and 101.100(h); disclosure requirements for food not accurately labeled for quantity of contents and for claiming certain labeling exemptions.	25,000	1.03	25,750	0.5 (30 minutes)	12,875
Nutritional labeling for new products	500	1	500	2	1,000
Total			1,513,799		1,030,258

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

Because of the consolidation of OMB control number 0910–0813, our estimate reflects an annual increase of 188,442 responses and 188,282 hours. These estimates are based on our experience with food labeling, related submissions of petitions, and informal communications with industry.

Dated: May 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10824 Filed 5–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0118]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prior Notice of Imported Food

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 June 19, 2020.

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 0910–0520. 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.

Prior Notice of Imported Food—21 CFR 1.278 to 1.285

OMB Control Number 0910–0520—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 added section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), which requires that FDA receive prior notice for food, including food for animals, that is imported or offered for import into the United States. Sections 1.278 through 1.282 of FDA regulations (21 CFR 1.278 through 1.282) set forth the requirements for submitting prior notice, §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting Agency review after FDA has refused admission of an article of food under section 801(m)(1) of the FD&C Act or placed an article of food under hold under section 801(l) of the FD&C Act, and § 1.285(i) sets forth the procedure for post-hold submissions.

Section 304 of the FDA Food Safety Modernization Act (Pub. L. 111–353) amended section 801(m) of the FD&C Act to require a person submitting prior notice of imported food, including food for animals, to report, in addition to other information already required, ''any country to which the article has been refused entry.'' Advance notice of imported food allows FDA, with the support of the U.S. Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. By requiring that a prior notice contain specific information that indicates prior refusals by any country and identifies the country or countries, the Agency may better identify imported food shipments that may pose safety and security risks to U.S. consumers.

This information collection enables FDA to make better informed decisions in managing the potential risks of imported food shipments into the United States. Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection may include importers, owners, ultimate consignees, shippers, and carriers.

FDA regulations require that prior notice of imported food be submitted electronically using CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS) (§ 1.280(a)(1)) or the FDA Prior Notice System Interface (PNSI) (Form FDA 3540) (§ 1.280(a)(2)). PNSI is an electronic submission system available on the FDA Industry Systems page at *https://www.access.fda.gov.* Information the Agency collects in the prior notice submission includes: (1) The submitter and transmitter (if different from the submitter); (2) entry type and CBP identifier; (3) the article of food, including complete FDA product code; (4) the manufacturer, for an article of food no longer in its natural state; (5) the grower, if known, for an article of food that is in its natural state; (6) the FDA Country of Production; (7) the name of any country that has refused entry of the article of food; (8) the shipper, except for food imported by international mail; (9) the country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed; (10) the anticipated arrival information or, if the food is imported by international mail, the U.S. recipient; (11) the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States; (12) the carrier and mode of transportation, except for food imported by international mail; and (13) planned shipment information, except for food imported by international mail (§ 1.281).

Much of the information collected for prior notice is identical to the information collected for FDA importer's entry notice, which has been approved under OMB control number 0910–0046. The information in an importer's entry notice is collected electronically via CBP's ABI/ACS at the same time the respondent files an entry for import with CBP. To avoid double counting the burden hours already counted in the importer's entry notice information collection, the burden hour analysis in table 1 reflects FDA's estimate of the reduced burden for prior notice submitted through ABI/ACS in column 6 entitled ''Average Burden per Response.''

In addition to submitting a prior notice, a submitter should cancel a prior notice and must resubmit the information to FDA if information changes after the Agency has confirmed a prior notice submission for review (*e.g.,* if the identity of the manufacturer changes) (§ 1.282). However, changes in the estimated quantity, anticipated arrival information, or planned shipment information do not require resubmission of prior notice after the Agency has confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to (iii)). In the event that FDA refuses admission to an article of food under section 801(m)(1) or the Agency places it under hold under section 801(l) of the FD&C Act, §§ 1.283(d) and 1.285(j) set forth the procedure for requesting FDA's review and the information required in a request for review. In the event that the Agency places an article of food under hold under section 801(l) of the FD&C Act, § 1.285(i) sets forth the procedure for, and the information to be included in, a post-hold submission.

In the **Federal Register** of February 6, 2020 (85 FR 6955), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but was not responsive to the four information collection topics solicited and therefore is not addressed.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Prior Notice Submissions: Through ABI/ACS						
1.280 through 1.281	N/A	1,700	7,647	12,999,900	0.167 (10 minutes)	[2] 2,170,983
Through PNSI						
1.280 through 1.281	[3] 3540	27,000	70	1,890,000	0.384 (23 minutes)	725,760

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

21 CFR section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subtotal						2,896,743
Cancellations: Through ABI/ACS						
1.282	3540	7,040	1	7,040	0.25 (15 minutes)	1,760
Through PNSI						
1.282 and 1.283(a)(5)	3540	35,208	1	35,208	0.25 (15 minutes)	8,802
Subtotal						10,562
Requests for Review and Post-hold Submissions						
1.283(d) and 1.285(j),	N/A	1	1	1	8	8
1.285(i)	N/A	263	1	263	1	263
Subtotal						271
Total				14,932,412		2,907,576

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] To avoid double counting, an estimated 396,416 burden hours already accounted for in the importer's entry notice information collection approved under OMB control number 0910–0046 are not included in this total.
[3] The term "Form FDA 3540" refers to the electronic submission system known as PNSI, which is available at *https://www.access.fda.gov.*

Based on our experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years, we have made no adjustments in our burden estimate for the information collection. We estimate that 1,700 users of ABI/ACS will submit an average of 7,647 prior notices annually, for a total of 12,999,900 prior notices received through ABI/ACS. We assume the reporting burden for a prior notice submitted through ABI/ACS to be 10 minutes, or 0.167 hour, per notice, for a total annual burden of 2,170,983 hours. This estimate takes into consideration the burden hours already counted in the information collection approval for FDA importer's entry notice (OMB control number 0910–0046), as previously discussed.

We estimate that 27,000 registered users of PNSI will submit an average of 70 prior notices annually, for a total of 1,890,000 prior notices received annually. We assume the reporting burden for a prior notice submitted through PNSI to be 23 minutes, or 0.384 hour, per notice, for a total burden of 725,760 hours.

We estimate that 7,040 users of ABI/ACS will submit an average of 1 cancellation annually, for a total of 7,040 cancellations received annually through ABI/ACS. We assume the reporting burden for a cancellation submitted through ABI/ACS to be 15 minutes, or 0.25 hour, per cancellation, for a total burden of 1,760 hours.

We estimate that 35,208 registered users of PNSI will submit an average of 1 cancellation annually, for a total of 35,208 cancellations received annually. We assume the reporting burden for a cancellation submitted through PNSI to be 15 minutes, or 0.25 hour, per cancellation, for a total burden of 8,802 hours.

We estimate that one or fewer requests for review under § 1.283(d) or § 1.285(j) will be submitted annually. We assume that it will take respondents 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, we estimate a total reporting burden of 8 hours.

We estimate that 263 post-hold submissions under § 1.285(i) will be submitted annually. We assume that it will take about 1 hour to prepare the written notification described in § 1.285(i)(2), for a total reporting burden of 263 hours.

Dated: May 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10825 Filed 5–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Research Education on Alzheimer's Disease and Related Dementias.

Date: June 4, 2020.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kimberly Firth, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda,