find out if interventions are reaching pregnant women and having the intended effects along with getting feedback from pregnant women about the Zika prevention activities that have been implemented (*e.g.,* Zika education sessions and prevention kits, vector control activities, and communication activities).

Findings will be used to improve the delivery of interventions and to inform decisions about future Zika prevention activities for pregnant women in Puerto Rico. The plan is to conduct up to 500 telephone interviews every two months over a 9-month period, (a total of four rounds), analyze the data, and generate a report for leaders of the response to offer insights on the delivery of interventions to pregnant women. The information will be used to make recommendations for improving interventions. Information may also be used to develop presentations, reports, and manuscripts to document the program and lessons learned in order to inform future programs of this sort.

The purpose of this assessment is also to assess core components of CDC's Zika response in communicating prevention behaviors, risk messages to the public about vector control activities, and the Zika Prevention kit.

The following factors will be assessed:

- Knowledge about Zika virus and related prevention behaviors
- Self-efficacy in engaging in Zika prevention behaviors
- Engagement in Zika prevention behaviors (*e.g.,* protective clothing use, condom use, and bed net use)
- Knowledge about, attitudes about, and use of the Zika Prevention Kit materials
- Knowledge about, attitudes about, and use of environmental vector control activities
- Risk perceptions of Zika
- Exposures to communications along with other factors that may be important considerations in their taking action or not (*e.g.,* does their house have screens, etc.)

CDC will conduct telephone interviews with a mix of closed-ended and open-ended questions with pregnant women. We estimate 2,000 pregnant women will participate in the project over a nine month period.

Another component of this project is to conduct qualitative inquiry to explore emerging issues related to vector control, sexual transmission, contraception, mental health/emotional support, service/support needs of families with babies affected by Zika, or vaccine communications (if applicable). While pregnant women will be the main focus of most inquiry, other audiences could include community leaders, community members, and health care providers. The goal is to identify specific unmet needs, which can then be shared with the Department of Health and other human service agencies. The plan is to hold up to 7 focus groups (with up to 10 persons each), or up to 20 in-depth individual interviews or up to 75 brief intercept interviews. A maximum of 75 individuals would participate in this part.

Results of this project will have limited generalizability. However, results of this evaluation should provide information that can be used to enhance and revise the existing program as well as offer lessons learned to inform infectious disease control programs that use education materials.

Authorizing legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241). There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) | Total burden (in hrs.) |
|---|---|---|---|---|---|
| Pregnant WIC participant | Initial Telephone Interview. | 2,000 | 1 | 20/60 | 667 |
| WIC participants, other families affected by Zika | Focus group | 70 | 1 | 120/60 | 140 |
| WIC participants, other families | In-depth Interviews | 20 | 1 | 60/60 | 20 |
| General population in Zika affected neighborhood. | Brief intercept interview | 75 | 1 | 10/60 | 13 |
| Total | | | | | 840 |

**Leroy A. Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2016–31737 Filed 12–29–16; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–1155]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our food labeling regulations and on Form FDA 3570, Model Small Business Nutrition Labeling Exemption Notice, which small businesses may use to claim the small business exemption from nutrition labeling.

**DATES:** Submit either electronic or written comments on the collection of information by February 28, 2017.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2013–N–1155 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling Regulations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Food Labeling Regulations—21 CFR Parts 101, 102, 104, and 105; OMB Control Number 0910–0381—Extension**

Our food labeling regulations require food producers to disclose to consumers and others specific information about themselves or their products on the label or labeling of their products. Related regulations require that food producers retain records establishing the basis for the information contained in the label or labeling of their products and provide those records to regulatory officials. Finally, certain regulations provide for the submission of food labeling petitions to us. We issued our food labeling regulations under parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) under the authority of sections 4, 5, and 6 of the Fair Packaging and Labeling Act (the 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 (the FD&C Act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the FD&C Act, which provides that 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. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the FD&C Act and the FPLA.

Section 101.3 of our food labeling regulations requires that the label of a food product in packaged form bear a statement of identity (*i.e.,* the name of the product), including, as appropriate, the form of the food or the name of the food imitated. Section 101.4 prescribes requirements for the declaration of ingredients on the label or labeling of food products in packaged form. Section 101.5 requires that the label of a food product in packaged form 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. Section 101.9 requires that nutrition information be provided for all food products intended for human consumption and offered for sale, unless an exemption in § 101.9(j) applies to the product. In particular, § 101.9(c)(2)(ii) requires that the amount of *trans* fatty acids present in a food must be declared on the nutrition label on a separate line immediately under the line for the declaration of saturated fat. Section 101.9(g)(9) provides that interested parties may submit to us requests for alternative approaches to nutrition labeling requirements. Finally, § 101.9(j)(18) provides that firms claiming the small business exemption from nutrition labeling must submit notice to us supporting their claim exemption. We developed Form FDA 3570 to assist small businesses in claiming the small business exemption from nutrition labeling. The form contains all the elements required by § 101.9(j)(18).

Section 101.10 requires that restaurants provide nutrition information, upon request, for any food or meal for which a nutrient content claim or health claim is made. Section 101.12(b) provides the reference amount that is used for determining the serving sizes for specific products, including baking powder, baking soda, and pectin. Section 101.12(e) provides that a manufacturer that adjusts the reference amount customarily consumed (RACC) of an aerated food for the difference in density of the aerated food relative to the density of the appropriate nonaerated reference food must be prepared to show us detailed protocols and records of all data that were used to determine the density-adjusted RACC. Section 101.12(g) requires that the label or labeling of a food product 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. Section 101.12(h) provides for the submission of petitions requesting that we change the reference amounts defined by regulation.

Section 101.13 requires that nutrition information be provided in accordance with § 101.9 for any food product for which a nutrient content claim is made. Under some circumstances, § 101.13 also requires the disclosure of other types of information as a condition for the use of a nutrient content claim. For example, under § 101.13(j), if the claim compares the level of a nutrient in the food with the level of the same nutrient in another ''reference'' food, the claim must also disclose the identity of the reference food, the amount of the nutrient in each food, and the percentage or fractional amount by which the amount of the nutrient in the labeled food differs from the amount of the nutrient in the reference food. It also requires that when this comparison is based on an average of food products, this information must be provided to consumers or regulatory officials upon request. Section 101.13(q)(5) requires that restaurants document and provide to appropriate regulatory officials, upon request, the basis for any nutrient content claims they have made for the foods they sell.

Section 101.14(d)(2) and (d)(3) provides for the disclosure of nutrition information in accordance with § 101.9 and, under some circumstances, certain other information as a condition for making a health claim for a food product. Section 101.15 provides that, if the label of a food product contains any representation in a foreign language, all words, statements, and other information required by or under authority of the FD&C Act to appear on the label must appear in both the foreign language and in English. Section 101.22 contains labeling requirements for the disclosure of spices, flavorings, colorings, and chemical preservatives in food products. Section 101.22(i)(4) sets forth disclosure and recordkeeping requirements pertaining to certifications for flavors designated as containing no artificial flavors. Section 101.30 specifies the conditions under which a beverage that purports to contain any fruit or vegetable juice must declare the percentage of juice present in the beverage and the manner in which the declaration is to be made.

Section 101.36 requires that nutrition information be provided for dietary supplements offered for sale, unless an exemption in § 101.36(h) applies. In particular, § 101.36(b)(2) requires that the amount of *trans* fatty acids present in dietary supplements must be declared on the nutrition label on a separate line immediately under the line for the declaration of saturated fat. Section 101.36(e) permits the voluntary declaration of the quantitative amount and the percent of Daily Value of a dietary ingredient on a ''per day'' basis in addition to the required ''per serving'' basis, if a dietary supplement label recommends that the dietary supplement be consumed more than once per day. Section 101.36(f)(2) cross-references the provisions in § 101.9(g)(9) for the submission to us of requests for alternative approaches to nutrition labeling requirements. Also, § 101.36(h)(2) cross-references the provisions in § 101.9(j)(18) for the submission of small business exemption notices. As noted previously, we developed Form FDA 3570 to assist small businesses in claiming the small business exemption from nutrition labeling. The form contains all the elements required by § 101.36(h)(2).

Section 101.42 requests that food retailers voluntarily provide nutrition information for raw fruits, vegetables, and fish at the point of purchase, and § 101.45 contains guidelines for providing such information. Also, § 101.45(c) provides for the submission to us of nutrient databases and proposed nutrition labeling values for raw fruit, vegetables, and fish for review and approval.

Sections 101.54, 101.56, 101.60, 101.61, and 101.62 specify information that must be disclosed as a condition for making particular nutrient content claims. Section 101.67 provides for the use of nutrient content claims for butter, and cross-references requirements in other regulations for information declaration (§ 101.4) and disclosure of information concerning performance characteristics (§ 101.13(d)). Section 101.69 provides for the submission of a petition requesting that we authorize a particular nutrient content claim by regulation. Section 101.70 provides for the submission of a petition requesting that we authorize a particular health claim by regulation. Section 101.77(c)(2)(ii)(D) requires the disclosure of soluble fiber per serving in the nutrition labeling of a food bearing a health claim about the relationship between soluble fiber and a reduced risk of coronary heart disease. Section 101.79(c)(2)(iv) requires the disclosure of the amount of folate in the nutrition label of a food bearing a health claim about the relationship between folate and a reduced risk of neural tube defects.

Section 101.100(d) provides that any agreement that forms the basis for an exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the FD&C Act be

in writing and that a copy of the agreement be made available to us upon request. Section 101.100 also contains reporting and disclosure requirements as conditions for claiming certain labeling exemptions (*e.g.,* 101.100(h)).

Section 101.105 specifies requirements for the declaration of the net quantity of contents on the label of a food in packaged form and prescribes conditions under which a food whose label does not accurately reflect the actual quantity of contents may be sold, with appropriate disclosures, to an institution operated by a Federal, State, or local government. Section 101.108 provides for the submission to us of a written proposal requesting a temporary exemption from certain requirements of §§ 101.9 and 105.66 for the purpose of conducting food labeling experiments with our authorization.

Regulations in part 102 define the information that must be included as part of the statement of identity for particular foods and prescribe related labeling requirements for some of these foods. For example, § 102.22 requires that the name of a protein hydrolysate will include the identity of the food source from which the protein was derived.

Part 104, which pertains to nutritional quality guidelines for foods, cross references several labeling provisions in part 101 but contains no separate information collection requirements.

Part 105 contains special labeling requirements for hypoallergenic foods, infant foods, and certain foods represented as useful in reducing or maintaining body weight.

The purpose of our food labeling requirements is to allow consumers to be knowledgeable about the foods they purchase. Nutrition labeling provides information for use by consumers in selecting a nutritious diet. Other information enables a consumer 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.

*Description of Respondents:* Respondents to this information collection are manufacturers, packers, and distributors of food products. Because of the existence of exemptions and exceptions, not all of the requirements apply to all food producers or to all of their products. Some of the regulations affect food retailers, such as supermarkets and restaurants.

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

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

| 21 CFR section | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| 101.3, 101.22, 102 and 104; statement of identity labeling requirements. | 25,000 | 1.03 | 25,750 | .5 (30 minutes) ..... | 12,875 |
| 101.4, 101.22, 101.100, 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 104; labeling requirements for disclosure of nutrition information. | 25,000 | 1.03 | 25,750 | .40 (24 minutes) ..... | 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), 101.13(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 |

TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN [1]—Continued

| 21 CFR section | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| 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), (h), (i), (k), and (q) of the FD&C Act. | 1,000 | 1 | 1,000 | 1 | 1,000 |
| 101.105 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 |
| Total | | | | | 1,029,258 |

[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 | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 101.12(e); recordkeeping to document the basis for density-adjusted RACC. | 25 | 1 | 25 | 1 | 25 |
| 101.13(q)(5); recordkeeping to document the basis for nutrient content claims. | 300,000 | 1.5 | 450,000 | 0.75 (45 minutes) | 337,500 |
| 101.14(d)(2); recordkeeping to document nutrition information related to health claims for food products. | 300,000 | 1.5 | 450,000 | 0.75 (45 minutes) | 337,500 |
| 101.22(i)(4); recordkeeping to document supplier certifications for flavors designated as containing no artificial flavors. | 25 | 1 | 25 | 1 | 25 |
| 101.100(d)(2); recordkeeping pertaining to agreements that form the basis for an exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the FD&C Act. | 1,000 | 1 | 1,000 | 1 | 1,000 |
| 101.105(t); recordkeeping pertaining to disclosure requirements for food not accurately labeled for quantity of contents. | 100 | 1 | 100 | 1 | 100 |
| Total | | | | | 676,150 |

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section/Form No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 101.9(j)(18) and 101.36(h)(2); procedure for small business nutrition labeling exemption notice using Form FDA 3570 | 10,000 | 1 | 10,000 | 8 | 80,000 |
| 101.12(h); petitions to establish or amend a RACC | 5 | 1 | 5 | 80 | 400 |
| 101.69; petitions for nutrient content claims | 3 | 1 | 3 | 25 | 75 |
| 101.70; petitions for health claims | 5 | 1 | 5 | 80 | 400 |

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

| 21 CFR section/Form No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 101.108; written proposal for requesting temporary exemptions from certain regulations for the purpose of conducting food labeling experiments | 1 | 1 | 1 | 40 | 40 |
| Total | | | | | 80,915 |

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

The estimated annual third party disclosure, recordkeeping, and reporting burdens are based on our communications with industry and our knowledge of and experience with food labeling and the submission of petitions and requests to us.

We expect that the burden hours for submissions under § 101.108 will be insignificant. Section 101.108 was originally issued to provide a procedure whereby we could grant exemptions from certain food labeling requirements. Exemption petitions have infrequently been submitted in the recent past; none have been submitted since publication on January 6, 1993, of the final regulations implementing section 403(q) and (r) of the FD&C Act. Thus, in order to maintain OMB approval of § 101.108 to accommodate the possibility that a food producer may propose to conduct a labeling experiment on its own initiative, we estimate that we will receive one or fewer submissions under § 101.108 in the next 3 years.

Dated: December 27, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–31733 Filed 12–29–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–D–0025]**

### Medical Device Accessories—Describing Accessories and Classification Pathway for New Accessory Types; Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Medical Device Accessories—Describing Accessories and Classification Pathways for New Accessory Types.'' This document provides guidance to industry and FDA staff about the regulation of accessories to medical devices. The guidance explains what devices FDA generally considers an ''accessory'' and encourages use of the *de novo* classification process under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to allow manufacturers and other parties to request risk- and regulatory control-based classification of accessories of a new type (*i.e.,* accessories of a type that has not been previously classified under the FD&C Act, cleared for marketing under a 510(k) submission, or approved in an application for premarket approval (PMA)).

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2015–D–0025 for ''Medical Device Accessories—Describing Accessories and Classification Pathway for New Accessory Types.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be