SUPPLEMENTARY INFORMATION:

I. Background

FDA has explained and clarified, through the guidance entitled, ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]'' (Ref. 1), how it makes substantial equivalence decisions under section 513(i)(1)(A) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(i)(1)(A)). Substantial equivalence is rooted in comparisons between new devices and predicate devices. However, the FD&C Act does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets or exceeds those levels of performance for the same characteristics, FDA could find the new device as safe and effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence with data showing the new device meets or exceeds the level of performance of appropriate predicate device(s). Under the approach expanded in this guidance, a submitter could satisfy the requirement to compare its device with a legally marketed device by, among other things, demonstrating conformance to performance criteria established in FDA-recognized consensus standards, FDA guidance, and/or special controls.

Use of this approach may also streamline the review of 510(k) submissions, thereby reducing burdens on the Agency and possibly review times on individual submissions. In addition, this approach may facilitate healthcare professionals and patients making better informed decisions, by helping ensure a device cleared through this pathway meets a transparent set of performance criteria. At the same time, this approach satisfies the statutory standard for demonstrating substantial equivalence. As a result, this expanded approach is intended to promote the public health by helping patients gain more timely access to new medical devices that are high quality, safe, and effective. FDA welcomes public input on device types for which FDA should consider identifying performance criteria and evidence-based suggestions on what the performance criteria should be.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria; Draft Guidance for Industry and Food and Drug Administration Staff.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This draft guidance document is also available at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria; Draft Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17038 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 807, subpart E have been approved under OMB control number 0910–0120 and the collections of information in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

V. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]—Guidance for Industry and Food and Drug Administration Staff,'' July 28, 2014, available at: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.*

Dated: April 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07564 Filed 4–11–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1030]

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

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 May 14, 2018.

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 0910–0792. 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 Allergen Labeling and Reporting

OMB Control Number 0910–0792—Extension

This information collection supports third-party disclosure requirements of food allergen labeling, as well as the reporting associated with the submission of petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food allergens under section 403(w)(6) and (7) of the FD&C Act (21 U.S.C. 343(w)(6) and (7)). The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II, Pub. L. 108–282) amended the FD&C Act by defining the term ''major food allergen'' and stating that foods regulated under the FD&C Act are misbranded unless they declare the presence of each major food allergen on the product label using the name of the food source from which the major food allergen is derived. Section 403(w)(1) of the FD&C Act sets forth the requirements for declaring the presence of each major food allergen on the product label. Section 201(qq) of the FD&C Act (21 U.S.C. 321(qq)) defines a major food allergen as ''[m]ilk, egg, fish (*e.g.,* bass, flounder, or cod), Crustacean shellfish (*e.g.,* crab, lobster, or shrimp), tree nuts (*e.g.,* almonds, pecans, or walnuts), wheat, peanuts, and soybeans'' and also as a food ingredient that contains protein derived from such foods. The definition excludes any highly refined oil derived from a major food allergen and any ingredient derived from such highly refined oil.

In some cases, the production of an ingredient derived from a major food allergen may alter or eliminate the allergenic proteins in that derived ingredient to such an extent that it does not contain allergenic protein. In addition, a major food allergen may be used as an ingredient or as a component of an ingredient such that the level of allergenic protein in finished food products does not cause an allergic response that poses a risk to human health. Therefore, FALCPA provides two mechanisms through which such ingredients may become exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. An ingredient may obtain an exemption through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(6) of the FD&C Act). Alternately, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient ''does not contain allergenic protein'' or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act (21 U.S.C. 348) that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(7) of the FD&C Act).

A. Third-Party Disclosure

The labeling requirements of section 403(w)(1) of the FD&C Act apply to all packaged foods sold in the United States that are regulated under the FD&C Act, including both domestically manufactured and imported foods. As noted, section 403(w)(1) of the FD&C Act requires that the label of a food product declare the presence of each major food allergen. We estimate the information collection burden of the third-party disclosure associated with food allergen labeling under section 403(w)(1) of the FD&C Act as the time needed for a manufacturer to review the labels of new or reformulated products for compliance with the requirements of section 403(w)(1) of the FD&C Act and the time needed to make any needed modifications to the labels of those products.

The primary user of the allergen information disclosed on the label or labeling of food products is the consumer that purchases the food product. Consumers will use the information to help them make choices concerning their purchase of a food product, including choices related to substances that the consumer wishes to avoid due to their potential to cause adverse reactions. Additionally, we intend to use the information to determine whether a manufacturer or other supplier of food products is meeting its statutory obligations. Failure of a manufacturer or other supplier of food products to label its products in compliance with section 403(w)(1) of the FD&C Act may result in a product being misbranded under the FD&C Act and the manufacturer or packer and the product subject to regulatory action.

B. Reporting

Under section 403(w)(6) and (7) of the FD&C Act, interested parties may request from us a determination that an ingredient is exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. An ingredient may obtain an exemption through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(6) of the FD&C Act). This section also states that the burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health. Alternately, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient ''does not contain allergenic protein'' or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(7) of the FD&C Act).

Our document entitled ''Food Allergen Labeling Exemption Petitions and Notifications: Guidance for Industry,'' sets forth our recommendations with regard to the information that an interested party should submit in such a petition or notification. The guidance states that to evaluate these petitions and notifications, we will consider scientific evidence that describes: (1) The identity or composition of the ingredient; (2) the methods used to produce the ingredient; (3) the methods used to characterize the ingredient; (4) the intended use of the ingredient in food; and (5) either (a) for a petition—data and information, including the expected level of consumer exposure to the ingredient, that demonstrate that the ingredient, when manufactured and used as described, does not cause an allergic response that poses a risk to human health; or (b) for a notification, data and information that demonstrate that the ingredient, when manufactured as described, does not contain allergenic protein, or documentation of a previous determination under a process under section 409 of the FD&C Act that the ingredient does not cause an allergic response that poses a risk to human health.

We use information submitted in petitions and notifications to determine whether the ingredient satisfies the criteria of section 403(w)(6) and (7) of the FD&C Act for granting the exemption.

In the **Federal Register** of December 12, 2017 (82 FR 58407), we published a

60-day notice inviting public comment on the proposed extension of this collection of information. One comment was received that expressed support for the information collection but did not otherwise respond to the topics solicited, nor did the comment suggest we revise our burden estimate. We therefore retain the currently approved estimate of the associated burden for the information collection, which is as follows:

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

FD&C act section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
403(w)(1); review labels for compliance with food allergen labeling requirements	77,500	1	77,500	1	77,500
403(w)(1); redesign labels to comply with food allergen labeling requirements	3,875	1	3,875	16	62,000
Total					139,500

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

Using a labeling cost model to estimate the number of new or reformulated products sold in the United States, annually, that are affected by the requirements of section 403(w)(1) of the FD&C Act, we estimate there are 690,000 Universal Product Codes (UPCs) of FDA-regulated foods and approximately 85,000 UPCs of FDA-regulated dietary supplements for a total of 775,000 UPCs. We assume an annual entry rate of 10 percent for new or reformulated UPCs (77,500), and assume 5 percent of labels may be redesigned (3,875). We estimate an average burden for the review of labels for compliance with the food allergen labeling requirements under section 403(w)(1) of the FD&C Act to be 1 hour, and we estimate 16 hours for the redesign of a label. Together we estimate a total annual hourly burden of 139,500 in third-party disclosure.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C act section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
403(w)(6); petition for exemption	5	1	5	100	500
403(w)(7); notification	5	1	5	68	340
Total					840

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

Based on the number of petitions and notifications received in recent years, we assume that we will receive five petitions and five notifications annually, over the next 3 years. Assuming an association of one respondent to each petition or notification, we estimate that five respondents will each submit one petition and five respondents will each submit one notification, as reported in table 2, rows 1 and 2.

We base our estimate of the average burdens per response reported in table 2 on our experience with other petition processes. We estimate that a petition would take, on average, 100 hours to develop and submit. Therefore, we estimate that the burden associated with petitions will be 500 hours annually (5 petitions $\times$ 100 hours per petition).

The burden of a notification involves collecting documentation that a food ingredient does not pose an allergen risk. Either we can make a determination that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409 of the FD&C Act, or the respondent would submit scientific evidence demonstrating that the ingredient when manufactured as described does not contain allergenic protein. We estimate that it would take a respondent 20 hours to prepare and submit a notification based on our determination under a process under section 409 of the FD&C Act that the ingredient does not cause an allergic response. We estimate that it would take a respondent approximately 100 hours to prepare a notification submitting scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein. We have no data on how many notifications would be based on our determination that the ingredient does not cause an allergic response or based on scientific evidence that demonstrates that the food ingredient does not contain allergenic protein. Therefore, we estimate that three of the five notifications would be based on scientific evidence, and two of the five notifications would be based on our determination. The average time per notification is then estimated to be 68 hours (2×20 hours + 3×100 hours)/5). Therefore, we estimate that the burden associated with notifications will be 340 hours annually (5 notifications $\times$ 68 hours per notification), as reported in table 2. The burden estimate has not increased since the initial OMB approval.

Dated: April 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07545 Filed 4–11–18; 8:45 am]

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