Estimated Total Annual Burden Hours: 3,149,174.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 9836A.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–11370 Filed 5–30–19; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0001]

Improving the Implementation of Risk-Based Monitoring Approaches of Clinical Investigations; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, we) is announcing the following pubic workshop entitled ''Improving the Implementation of Risk-Based Monitoring Approaches of Clinical Investigations.'' This public workshop is convened by Duke University's Robert J. Margolis, MD, Center for Health Policy and supported by a cooperative agreement with FDA. The purpose of the public workshop is to capture stakeholder experiences with risk-based approaches to monitoring of clinical investigations and gather stakeholder input on opportunities to further the implementation of risk-based approaches to monitoring.

DATES: The public workshop will be held on July 17, 2019, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the Marriott Marquis Washington, DC at 901 Massachusetts Ave. NW, in Washington DC. For additional travel and hotel information, please refer to the following website: *https://healthpolicy.duke.edu/events/improving-implementation-risk-based-monitoring-approaches-clinical-trials.* There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Workshop*).

FOR FURTHER INFORMATION CONTACT: Raymond Chiang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2232, Silver Spring, MD 20993, 301–796–1940, *Raymond.Chiang@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

To support greater implementation of risk-based approaches to monitoring (RBM) of clinical investigations, FDA issued draft guidance for industry in March 15, 2019 (84 FR 9531) entitled ''A Risk-Based Approach to Monitoring of Clinical Investigations: Questions and Answers, '' which is available at *https://www.fda.gov/media/121479/download.* This draft guidance expands on the guidance for industry entitled, ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' (August 2013) by providing additional guidance to facilitate sponsors' implementation of risk-based monitoring.

Traditionally, sponsors and research organizations have depended upon on-site monitoring and 100 percent source data verification for each clinical site, an approach that is resource intensive and may contribute to increased clinical trial costs. Adoption of RBM could lead to improvements to human subject protections, data integrity, and the efficiency of clinical investigations.

Data suggest that RBM has not yet been widely implemented. Therefore, FDA is seeking additional feedback from stakeholders on the challenges, barriers, and enablers that might be impacting the adoption of RBM. The public workshop addressed in this document is being held to capture stakeholder experiences with risk-based approaches to monitoring of clinical investigations and to gather stakeholder input on ways to improve the implementation of risk-based approaches to monitoring.

II. Topics for Discussion at the Public Workshop

During the public workshop, speakers and participants will cover a range of issues related to implementation of risk-based approaches to monitoring. Topics for discussion will include, and are not limited to, challenges to implementation of RBM, enablers to support implementation of RBM, and lessons learned from strategies employed to implement RBM.

III. Participating in the Public Workshop

Registration: To register for the public workshop, complete the registration form at *https://healthpolicy.duke.edu/events/improving-implementation-risk-based-monitoring-approaches-clinical-trials.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by July 16, 2019, by 5 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been registered. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact the Duke-Margolis Center for Health Policy (phone: 202–791–9561, email: *margolisevents@duke.edu*) no later than July 10, 2019.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast and archived video footage will be available at the event website. Persons interested in viewing the live webcast are encouraged to register in advance (see *Registration*). The live webcast will also be available at the website above on the day of the event without preregistration. Registered webcast participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements prior to joining the streaming webcast of the public workshop.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Meeting Materials: All event materials will be provided to registered attendees via email prior to the workshop and will be publicly available at the Duke-Margolis Center for Health Policy website: *https://healthpolicy.duke.edu/*

events/improving-implementation-risk-based-monitoring-approaches-clinical-trials.

Transcripts: Please be advised that transcripts of the public workshop will not be available.

Dated: May 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–11411 Filed 5–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0032]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 July 1, 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 0910–0331. 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; Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93

OMB Control Number 0910–0331—Extension

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(r)(6)) and § 101.93 (21 CFR 101.93) of our regulations require that, no later than 30 days after the first marketing, we be notified by the manufacturer, packer, or distributor of a dietary supplement that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the FD&C Act. In accordance with these requirements, submissions must include: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) the signature of a responsible individual or the person who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Our electronic form (Form FDA 3955) allows respondents to the information collection to electronically submit notifications to FDA via an electronic system. We are upgrading our current system (the FDA Unified Registration Listing System known as FURLS) to deploy the Food Applications Regulatory Management (FARM) system. FARM is modeled after FURLS and collects the same information, but improves our operational efficiency. A web link of the FARM system can be found here: *https://www.fda.gov/Food/DietarySupplements/IndustryInfo/ucm485532.htm.* Firms that prefer to submit a paper notification in a format of their own choosing still have the option to do so; however, Form FDA 3955 prompts respondents to include certain elements in their structure/function claim notification (SFCN) described in § 101.93 in a standard electronic format and helps respondents organize their SFCN to include only the information needed for our review of the claim. Note that the SFCN, whether electronic or paper, is used for all claims made pursuant to section 403(r)(6) of the FD&C Act, including nutrient deficiency claims and general well-being claims in addition to structure/function claims. The electronic form, and any optional elements prepared as attachments to the form (*e.g.,* label), can be submitted in electronic format. Submissions of SFCNs will continue to be allowed in paper format. We use this information to evaluate whether statements made for dietary ingredients or dietary supplements are permissible under section 403(r)(6) of the FD&C Act.

In the **Federal Register** of February 7, 2019 (84 FR 2528), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Description of Respondents: Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

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
101.93	3,690	1	3,690	0.75 (45 minutes)	2,767.5

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

Our burden estimate reflects an overall increase of 1,117.5 hours (from 1,650 hours) and a corresponding increase of 1,490 responses (from 2,200 responses). We attribute this adjustment to an increase in the average number of notification submissions we received over the preceding 12 months, which we expect will continue over the next 3 years. We believe gathering information to satisfy the notification requirements of section 403(r)(6) of the FD&C Act by