patient expanded access requests are provided under § 312.310(b), and the requirements for requesting individual patient expanded access for emergency use are provided under § 312.310(d). FDA currently has OMB approval under control number 0910–0014 for individual patient expanded access information collection under §§ 312.305(b), 312.310(b), and 312.310(d). The submission requirements concerning the use of Form FDA 3926 for certain followup reports are provided under §§ 312.32(c), 312.32(d), 312.33, 312.310(c)(2), 312.30, 312.41, and 312.42(e).

The estimates for ''number of respondents,'' ''number of responses per respondent,'' and ''total annual responses'' were obtained from the Center for Drug Evaluation and Research (CDER) reports and data management systems and from other sources familiar with the number of submissions received for individual patient expanded access use under part 312. The estimates for ''average burden per response'' were based on information provided by CDER and other Department of Health and Human Services personnel who are familiar with preparing and reviewing expanded access submissions by practicing physicians.

Based on data for the number of submissions to FDA during 2011, 2012, and 2013, we originally estimated that approximately 790 licensed physicians would use Form 3926 to submit 1.46 requests per physician (respondent) for individual patient expanded access, for a total of 1,153 responses annually. In response to comments received, FDA clarifies in the final guidance and in the form instructions that licensed physicians may also use Form FDA 3926 for certain followup submissions. Based on data for the number of followup submissions during 2011, 2012, and 2013, FDA estimates that about 790 physicians will each use Form FDA 3926 to submit 1.57 followup submissions per physician, for approximately 1,241 followup responses annually. Based on these estimates, FDA calculates the total annual responses to be 2,394 (1,153 requests for individual patient expanded access and 1,241 followup submissions) by 790 physicians for an average of 3.03 responses per respondent. FDA estimates the average burden per response to be 45 minutes (0.75 hour). Based on this estimate, FDA calculates the total burden to be 1,795 hours. Under OMB control number 0910–0014, FDA currently has OMB approval of 17,592 hours for these submissions. The use of FDA Form 3926 will reduce the current burden by 15,797 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance on individual patient expanded access applications: Form FDA 3926	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Expanded access submission for treatment of an individual patient, including submission of Form FDA 3926.	790	3.03	2,394	0.75 (45 minutes).	1,795

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

Dated: March 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05491 Filed 3–10–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0221]

Agency Information Collection Activities; Proposed Collection; 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 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 invites comments on the information collection provisions of the regulation requiring the manufacturer, packer, or distributor of a dietary supplement to notify us that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The notice also invites comment on a new electronic form that allows manufacturers, packers, and distributors of dietary supplements to notify us via FDA's Unified Registration and Listing System (FURLS).

DATES: Submit either electronic or written comments on the collection of information by May 10, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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–2009–N–0221 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://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 *http://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 *http://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.

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, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our 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; Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93

OMB Control Number 0910–0331—Extension

Section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) and its implementing regulation, 21 CFR 101.93, require that 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. These provisions require that we be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (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.

We have developed an electronic form (Form FDA 3955) that interested persons will be able to use to electronically submit their notifications to FDA via FURLS. Firms that prefer to submit a paper notification in a format of their own choosing will still have the option to do so, however. Form FDA 3955 prompts a respondent to include certain elements in their structure/function claim notification (SFCN) described in § 101.93 in a standard format electronically and helps the respondent 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 that would be prepared as attachments to the form (*e.g.,* label), can be submitted in electronic format via FURLS. 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. Draft screenshots of Form FDA 3955 and instructions are available for comment at *http://www.fda.gov/Food/DietarySupplements/IndustryInfo/ucm485532.htm.*

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	2,200	1	2,200	0.75 (45 minutes)	1,650

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

We believe that there will be minimal burden on the industry to generate information to meet the notification requirements of section 403(r)(6) of the FD&C Act by submitting information regarding section 403(r)(6) of the FD&C Act statements on labels or in labeling of dietary supplements. We also believe that submission via FURLS will not affect the burden estimates. We are requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. We estimate that, each year, approximately 2,200 firms will submit the information required by section 403(r)(6) of the FD&C Act. This estimate is based on the average number of notification submissions received by us in the preceding 3 years. We estimate that a firm will require 0.75 hours to gather the information needed and prepare a communication to us, for a total of 1,650 hours (2,200 × 0.75).

Dated: March 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05478 Filed 3–10–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Division of Intramural Research Board of Scientific Counselors, NIAID.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Division of Intramural Research Board of Scientific Counselors, NIAID.

Date: June 6–7, 2016.

Time: 7:30 a.m. to 10:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 50, Rooms 1227 and 1223, 50 Center Drive, Rockville, MD 20852.

Contact Person: Hugh J. Auchincloss, MD, Deputy Director, NIAID Deputy Director, National Inst. of Allergy and Infectious Diseases, National Institutes of Health, Building 31, Room 7A03, MSC 2520, Bethesda, MD 20892–2520, 301–496–9677, *auchinclossh@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 7, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–05429 Filed 3–10–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Study To Estimate Radiation Doses and Cancer Risks From Radioactive Fallout From the Trinity Nuclear Test—National Cancer Institute (NCI)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Steve Simon, Dosimetry Unit Head and Staff Scientist, Radiation Epidemiology Branch, Division of Cancer Epidemiology & Genetics, National Cancer Institute, NIH, 9609 Medical Center Drive, MSC9778, Bethesda, MD 20892–9778 or call non-toll-free number (240)-276–7371 or Email your request, including your address to: *ssimon@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Study to Estimate Radiation Doses and Cancer Risks from Radioactive Fallout from the Trinity Nuclear Test, 0925–NEW, New Submission, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This research plan is for a radiation-related cancer risk projection study for the residents of the state of New Mexico (NM) potentially exposed to radioactive fallout from the Trinity nuclear test conducted in 1945. Data will be collected on diet and lifestyle from three groups in NM (non-Hispanic white, Hispanic, and Native American)