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; Submission for Office of Management and Budget Review; Food Labeling; Notification Procedures for Statements on Dietary Supplements

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 (the PRA).

DATES: Fax written comments on the collection of information by [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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 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 us via FDA's Unified Registration and Listing System (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.

In the Federal Register of March 11, 2016 (81 FR 12910), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment in support of the information collection.

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. 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: May 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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