TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total					882,203

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

Dated: February 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03881 Filed 2–24–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0878]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient

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 (the PRA).

DATES: Fax written comments on the collection of information by March 27, 2015.

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 0910–0330. 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.

Premarket Notification for a New Dietary Ingredient—21 CFR 190.6 (OMB Control Number 0910–0330)—Extension

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350b(a)) provides that at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient, the manufacturer or distributor of the dietary supplement or of the new dietary ingredient is to submit to us (as delegate for the Secretary of Health and Human Services) information upon which the manufacturer or distributor has based its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. FDA's implementing regulation, 21 CFR 190.6, requires this information to be submitted to the Office of Nutrition, Labeling, and Dietary Supplements (ONLDS) in the form of a notification. Under § 190.6(b), the notification must include the following: (1) The name and complete address of the manufacturer or distributor, (2) the name of the new dietary ingredient, (3) a description of the dietary supplement(s) that contain the new dietary ingredient, including the level of the new dietary ingredient in the dietary supplement and the dietary supplement's conditions of use, (4) the history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of the dietary supplement, and (5) the signature of a responsible person designated by the manufacturer or distributor.

These premarket notification requirements are designed to enable us to monitor the introduction into the marketplace of new dietary ingredients and dietary supplements that contain new dietary ingredients, in order to protect consumers from ingredients and products whose safety is unknown. We use the information collected in new dietary ingredient notifications to evaluate the safety of new dietary ingredients in dietary supplements and to support regulatory action against ingredients and products that are potentially unsafe.

We are developing an electronic portal that interested persons will be able to use to electronically submit their notifications to ONLDS via FDA 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 3880 prompts a submitter to input the elements of a new dietary ingredient notification (NDIN) in a standard format and helps the submitter organize its NDIN to focus on the information needed for our safety review. Safety information will be submitted via a supplemental form entitled ''New Dietary Ingredient (NDI) Safety Information.'' This form provides a standard format to describe the history of use or other evidence of safety on which the manufacturer or distributor bases its conclusion that the new dietary ingredient will be reasonably expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement, as well as related identity information that is necessary to demonstrate safety by showing that the new dietary ingredient and dietary supplement(s) that are the subject of the notification are the same or similar to the ingredients and products for which safety data and information have been provided. Draft screenshots of Form FDA 3880 and the supplemental safety information form are available for comment at *http://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/ucm356620.htm.*

Description of Respondents: The respondents to this collection of information are manufacturers and distributors in the dietary supplement industry; specifically, firms that manufacture or distribute new dietary ingredients or dietary supplements that contain a new dietary ingredient.

In the **Federal Register** of November 14, 2014 (79 FR 68275), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. We received three comments in response to the notice. Two of the comments were unrelated to the PRA, and therefore we did not consider them.

The third comment asserted that we underestimated the reporting burden of the NDIN procedures under § 190.6 by failing to take into account the recommendations in the draft guidance entitled ''Dietary Supplements: New Dietary Ingredient Notifications and Related Issues'' (the 2011 draft guidance) (available at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm257563.htm*). FDA announced the availability of the 2011 draft guidance for comment in a notice published in the **Federal Register** of July 5, 2011 (76 FR 39111).

Although we agree with the commenter that information collection recommendations in guidance are subject to the PRA, we intend to meet our PRA obligations in that regard separately at a later time. The 2011 draft guidance was published solely for the purpose of seeking comment, and it has not been made final. Moreover, FDA intends to publish a revised draft guidance for comment later this year, and the revised draft guidance will supersede the 2011 draft guidance. Although we expect the revised draft guidance to be followed by a final guidance, there will be an interim period where no guidance on NDINs is in effect. The purpose of the current PRA proceeding is to seek comment on and obtain OMB approval for the NDIN collections of information in effect during this interim period, which are those found in the FDA's NDIN regulations at § 190.6 and in the electronic NDIN submission forms that we have made available for comment. After publishing a revised draft guidance on NDINs and related issues, we intend to publish a 60-day notice inviting comment on the proposed collections of information associated with that document. At that time, we will carefully evaluate all comments we receive.

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
190.6	55	1	55	20	1,100

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

We believe that the burden of the premarket notification requirement on industry is limited and reasonable because we are requesting only safety and identity information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in compliance with the FD&C Act. In the past, commenters have argued that our burden estimate is too low. We carefully considered the issue and believe that burden estimates of greater than 20 hours per notification likely include the burden associated with researching and generating safety data for a new dietary ingredient. Under section 413(a)(2) of the FD&C Act, a dietary supplement that contains a new dietary ingredient is deemed to be adulterated unless there is a history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement. This requirement is separate from and additional to the requirement to submit a premarket notification for the new dietary ingredient. FDA's regulation on NDINs, § 190.6(a), requires the manufacturer or distributor of the dietary supplement, or of the new dietary ingredient, to submit to FDA the information that forms the basis for its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. Thus, § 190.6 only requires the manufacturer or distributor to extract and summarize information that should have already been developed to meet the safety requirement in section 413(a)(2) of the FD&C Act. We estimate that extracting and summarizing the relevant information from what exists in the company's files and presenting it in a format that meets the requirements of § 190.6 will take approximately 20 hours of work per notification. However, we seek comments on this estimate. We encourage comments offering alternative burden estimates to include documentation to support the alternative estimate.

We further estimate that 55 respondents will submit 1 premarket notification each. We base our estimate of the number of respondents on notifications received over the past 3 years, which averaged about 55 notifications per year.

Dated: February 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0230]

Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices.'' This draft guidance provides industry and Agency staff with recommendations regarding the technical performance assessment data that should be provided for regulatory evaluation of a digital whole slide imaging (WSI) system. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 26, 2015.

ADDRESSES: An electronic copy of the guidance document is available for