4164-01-P

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) 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 (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 0910-0330. 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.

Premarket Notification for a New Dietary Ingredient--21 CFR 190.6

OMB Control Number 0910-0330--Extension

This information collection supports Agency regulations and accompanying guidance. Specifically, section 413(a) of the Federal Food, Drug, and Cosmetic Act (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 FDA (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, § 190.6 (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. FDA uses 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.

FDA has developed an electronic portal that respondents may use to electronically submit their notifications to ONLDS via FDA Unified Registration and Listing Systems. 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 3880 prompts a submitter to input the elements of a new dietary ingredient notification (NDIN) in a standard format and helps the respondent organize its NDIN to focus on the information needed for FDA's safety review. Safety information may be submitted via a supplemental form entitled "New Dietary Ingredient 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 is 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. We continue to invite comment on Form FDA 3880 and the supplemental safety information form, which may be found on our website at https://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/default.htm.

In the *Federal Register* of November 17, 2017 (82 FR 54355), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. One comment suggested ways FDA might assist respondents by developing "specific guidance pertaining to the use and submission of master files to help determine whether a dietary ingredient should be the subject of an NDIN or exempted from notification." A second comment suggested that FDA: (1) failed to account for the cost of removing from the market dietary supplements suddenly deemed New Dietary Ingredients for the first time in the Guidance[2]; (2) substantially underestimated the number and cost of New Dietary Ingredient submissions that must be filed to comply with the Guidance; and (3) grossly and dangerously undervalued the economic impact the Guidance will have on the dietary supplement industry and the economy as a whole.

FDA appreciates this feedback. As noted, FDA has issued a draft guidance on Dietary Supplements: New Dietary Ingredient Notifications and Related Issues and will take the comment on additional guidance into consideration when finalizing the draft guidance. As resources allow, FDA may consider revised or additional guidance to assist respondents to the information collection. Relatedly, with regard to comments about costs or economic impact, FDA notes that, consistent with our regulations at 21 CFR part 10.115 (Good Guidance Practices), recommendations found in the draft guidance document are for comment only. In addition, the data analysis proffered regarding costs does not provide a basis upon which we can revise our burden estimate under the PRA. Notices published in the *Federal Register* in compliance with the PRA seek to improve information collection activities by evaluating our need for the information discussed in the notice and specific ways we might utilize technology

[2] The "Guidance" refers to a draft guidance published for comment in August 2016 and available at: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm257563.htm.

and/or enhance our collection techniques and mechanisms to minimize burden on respondents who are subject to the applicable regulatory requirements.

We therefore retain the following estimate:

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 (in Hours)	Total Hours
190.6; Dietary Supplements	55	1	55	20	1,100

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

We have made no adjustments to the currently approved burden estimate for the information collection. While we have received comments previously suggesting our burden estimate may be too low, the comments did not discuss the basis for such a conclusion. We therefore specifically invite individual respondent experience with the information collection and associated collection burden.

Based on our experience with the information collection over the past 3 years, we estimate that 55 respondents will submit 1 premarket notification each. We assume that extracting and summarizing relevant information from existing files and presenting it in a format that meets the requirements of § 190.6 will take approximately 20 hours of work per notification. We have carefully considered the burden associated with the premarket notification requirement and believe that estimates greater than 20 hours are likely to include burden associated with researching and generating safety data for a new dietary ingredient. We believe that the burden of the premarket notification requirement on industry is minimal 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. 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 new dietary ingredient notifications, § 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.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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