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, Agency, 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: Submit written comments (including recommendations) 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 submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 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

This information collection supports Agency regulations. Under section 413(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350b(a)), the manufacturer or distributor of a new dietary ingredient (NDI), or of the dietary supplement that contains the NDI, must submit a premarket notification to FDA (as delegate for the Secretary of Health and Human Services) at least 75 days before introducing the product into interstate commerce or delivering it for introduction into interstate commerce, unless the NDI and any other dietary ingredients in the dietary supplement "have been present in the food supply as an article used for food in a form in which the food has not been chemically altered" (21 U.S.C. 350b(a)(1)). The notification must contain the information which provides the basis on which the manufacturer or distributor of the NDI or dietary supplement has concluded that the dietary supplement containing the NDI will reasonably be expected to be safe (21 U.S.C. 350b(a)(2)).

FDA's implementing regulation, § 190.6 (21 CFR 190.6), specifies the procedure for submitting a premarket NDI notification and the information the manufacturer or distributor must include in the 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 NDI; (3) a description of the dietary supplement(s) that contains the NDI, including the level of the NDI in the dietary supplement and the conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the supplement's labeling, the ordinary conditions of use of the supplement; (4) the history of use or other evidence of safety establishing that the NDI 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 NDIs and dietary supplements that contain NDIs in order to protect consumers from ingredients and products whose safety is unknown. We use the

information collected in NDI notifications to evaluate the safety of NDIs in dietary supplements and to support regulatory action against ingredients and products that are potentially unsafe.

FDA developed an electronic portal (Form FDA 3880) that respondents may use to electronically submit their notifications to us via the Center for Food Safety and Applied Nutrition (CFSAN) Online Submission Module (COSM). COSM was developed to assist respondents when filing regulatory submissions and is specifically designed to aid users wishing to file submissions with CFSAN. COSM allows safety and other information to be uploaded and submitted online via Form FDA 3880. 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 NDI is reasonably expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement, as well as a description of the ingredient and other information. Firms that prefer to submit a paper notification in a format of their own choosing have the option to do so; however, Form FDA 3880 prompts a submitter to input the elements of an NDI notification in a standard format that we will be able to review efficiently. Form FDA 3880 may be accessed at https://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/default.htm.

Description of Respondents: The respondents to this collection of information are certain manufacturers and distributors in the dietary supplement industry.

In the *Federal Register* of October 16, 2020 (85 FR 65830), we published a 60-day notice requesting public comment on the proposed collection of information. A number of comments were received expressing general interest in labeling requirements applicable to dietary supplements. Other comments were received pertaining to related Agency draft guidance, one suggesting 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) 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.

While we appreciate all feedback regarding Agency information collection activities, as we communicated in our notice of March 28, 2018 (83 FR 13281), the data analysis offered by the comment does not provide a basis upon which we can revise our burden estimate under the PRA. Regulatory requirements regarding premarket notification for new dietary ingredients are set forth under 21 CFR 190.6 and were established by final rule of September 23, 1997 (62 FR 49886). 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 and/or enhance our collection techniques and mechanisms to minimize burden on respondents who are subject to applicable those requirements. Finally, notices of availability for Agency guidance documents are published consistent with regulations in 21 CFR 10.115 (Good Guidance Practices), which provide for public comment at any time.

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; Dietary Supplements	55	1	55	20	1,100

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

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 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. We believe that the burden of the premarket notification requirement on industry is 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 the NDI is in compliance with the FD&C Act.

If the required premarket notification is not submitted to FDA, section 413(a) of the FD&C Act provides that the dietary supplement containing the NDI is deemed to be adulterated under section 402(f) of the FD&C Act (21 U.S.C. 342(f)). Even if the notification is submitted as required, the dietary supplement containing the NDI is adulterated under section 402(f) of the FD&C Act unless there is a history of use or other evidence of safety establishing that the NDI, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. This requirement is separate from and additional to the requirement to submit a premarket notification for the NDI. FDA's regulation on NDI notifications, § 190.6(a), requires the manufacturer or distributor of the dietary supplement or of the NDI to submit to FDA the information that forms the basis for its conclusion that a dietary supplement containing the NDI 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.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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