radiopharmaceuticals, or both, we estimate that six submissions will be received annually and that 2,000 hours would be spent preparing the portions of the application that would be affected by this information collection. We further estimate the total time needed to prepare complete applications for diagnostic radiopharmaceuticals as approximately 12,000 hours. This information collection does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours, because safety and effectiveness information is already required in § 314.50 and has been approved under OMB control number 0910–0001. In fact, clarification of our criteria for the evaluation of diagnostic radiopharmaceuticals in this information collection is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies.

In table 1, row 2, we estimate the annual reporting burden for preparing the safety and effectiveness sections of a supplement to an approved application. This estimate does not include the time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Based on past submissions of human drug applications, new indication supplements for diagnostic radiopharmaceuticals, or both, we estimate that nine submissions will be received annually. We estimate the total time needed to prepare complete applications for supplements to new applications for diagnostic radiopharmaceuticals as approximately between 500 and 1,000 hours. We calculated the median of this estimate to arrive at approximately 750 hours. We further estimate that the total time needed to prepare the portions of the application that would be affected by this information collection as 6,750. As previously stated, this information collection does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 750 hours, because safety and effectiveness information is already required in § 314.50 and has been approved under OMB control number 0910–0001.

In the **Federal Register** of November 12, 2020 (85 FR 71923), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR NDAS AND SUPPLEMENTS TO APPROVED NDAS FOR DIAGNOSTIC RADIOPHARMACEUTICALS[1]

Manufacturers' activity (21 CFR Section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
NDAs (§§ 315.4, 315.5, and 315.6)	6	1	6	2,000	12,000
Supplements to Approved NDAs (§§ 315.4, 315.5, and 315.6)	9	1	9	750	6,750
Total					18,750

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

Our estimated burden for the information collection reflects an overall increase of 13 responses with a corresponding increase of 14,750 burden hours, including submissions involving NDAs. We attribute this adjustment to an increase in the number of submissions for NDAs for diagnostic radiopharmaceuticals we received over the past few years and because we are now capturing supplements to approved NDAs for diagnostic radiopharmaceuticals.

Dated: April 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07639 Filed 4–13–21; 8:45 am]

BILLING CODE 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 May 14, 2021.

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

OMB Control Number 0910–0330—Extension

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.

[FR Doc. 2021–07641 Filed 4–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1565]

Mark Reinhard: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Mark Reinhard from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Reinhard was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Reinhard was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred within the timeframe prescribed by regulation. Mr. Reinhard has not responded to the notice. Mr. Reinhard's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable April 14, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM–4029), Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On March 28, 2019, Mr. Reinhard entered a plea of guilty to one count of engaging in unlicensed wholesale distribution of prescription drugs in violation of sections 301(t), 303(b)(1)(D), and 503(e)(1)(A) of the FD&C Act (21 U.S.C. 331(t), 333(b)(1)(D), and 353(e)(1)(A)) and (18 U.S.C. 2), a felony offense under Federal law. On January 16, 2020, judgment of conviction was entered against Mr. Reinhard for this felony offense in the U.S. District Court for the Western District of Kentucky, Louisville Division.

The factual basis for this conviction is as follows: Mr. Reinhard was a pharmacist residing in the State of West Virginia and was employed by Meds 2 Go Express Pharmacy, Inc. (Meds 2 Go Express). From November 2010 through at least August 2012, he aided and abetted others, through Meds 2 Go Express, by engaging in unlicensed wholesale distribution of Tramadol from West Virginia to Alabama through Kentucky. Specifically, Mr. Reinhard aided and abetted individuals who combined, conspired, confederated, and agreed to engage in a scheme to sell, distribute, and dispense prescription drugs over the internet and to deliver those prescription drugs to customers, without the issuance of valid prescriptions. Under this scheme, customers would order prescription drugs from websites without ever seeing or speaking to a physician or medical practitioner. On the website, customers chose which prescription drugs they wished to order, and completed an online medical questionnaire with prepopulated answers that did not disqualify the customers from receiving the prescription drugs that they ordered. The website operator would then send the completed online medical questionnaires to doctors or individuals posing as doctors, who issued the prescriptions requested by the customers without first conducting an in-person medical examination, speaking with the customers, reviewing the customers' medical records, or otherwise verifying any of the information provided by the customer. These invalid prescriptions were issued outside of the usual course of professional practice and were not for a legitimate medical purpose. The website operators would then send the issued prescription by electronic means to pharmacies, including Meds 2 Go Express, to be filled. After filling a prescription, Meds 2 Go Express and other pharmacies would send the prescription drugs to the customers, who often were not in the same State as the pharmacy, via the U.S. Postal Service or other delivery methods. It was found that Mr. Reinhard distributed