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

the prescription drug Tramadol from West Virginia to a wholesale fulfillment pharmacy located in Alabama through Kentucky in violation of Federal law. Tramadol, as contained in the drug product ULTRAM and generic formulations, is a prescription painkiller that may induce psychic and physical dependence.

Based on this conviction, FDA sent Mr. Reinhard by certified mail on October 5, 2020, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Reinhard was convicted, as set forth in section 306(*l*)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Reinhard an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to file a timely request for a hearing would constitute an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Reinhard received the proposal on October 10, 2020. He did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Reinhard has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Reinhard is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and (c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Reinhard during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Reinhard provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Reinhard during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Reinhard for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2020–N–1565 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: April 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07638 Filed 4–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–0263]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 14, 2021.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0263–30D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, or Email: *Sherrette.funn@hhs.gov,* or call 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: The Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption Form.

Type of Collection: Extension.

OMB No. 0990–0263 Office of the Assistant Secretary for Health, Office for Human Research Protections.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption Form, OMB No. 0990–0263.

The information collected on the form is to provide a simplified procedure for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to satisfy the requirements of HHS regulations for the protection of human subjects at 45 CFR 46.103 for assurance identification and IRB certification and declare exemption status.

Likely Respondents: Institutions engaged in research involving human subjects where the research is supported by HHS. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule), which is codified for HHS at 45 CFR part 46, subpart A.