Authority: Section 2008 of the Social Security Act as enacted by Section 5507 of the Affordable Care Act.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–28018 Filed 12–26–18; 8:45 am]

BILLING CODE 4184–72–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1989]

Ranjan Bhandari: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Ranjan Bhandari, MD (Dr. Bhandari), for a period of 3 years 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 Dr. Bhandari was convicted of a misdemeanor under the FD&C Act for causing the introduction or delivery for introduction into interstate commerce of prescription drugs that were misbranded. In addition, FDA has determined that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. Dr. Bhandari was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Bhandari failed to request a hearing. Dr. Bhandari's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective December 27, 2018.

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.

FOR FURTHER INFORMATION CONTACT: Kenny Shade (ELEM–4144), Division of Enforcement, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits debarment of an individual if FDA finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On December 9, 2013, in the U.S. District Court for the Northern District of Ohio, judgment was entered against Dr. Bhandari after he entered a plea of guilty to one count of misbranding in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(a)), which is a misdemeanor offense under section 303(a)(1) of the FD&C Act (21 U.S.C. 333(a)(1)). FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for this conviction is as follows: Between June 1, 2006, and March 31, 2008, Dr. Bhandari was a physician (oncologist) in Ohio. During this time, Dr. Bhandari purchased and received oncology drugs, including ZOMETA, IRINOTECAN, ELOXATIN, GEMZAR, HYCAMTIN, ARANESP, and TAXOTERE, from a drug distributor located in Canada. These new drugs originated outside the United States and were not approved by FDA for introduction or delivery for introduction into interstate commerce in the United States. Thus, Dr. Bhandari caused the introduction or delivery for introduction into interstate commerce of prescription drugs that were misbranded for lacking adequate directions for use in their labeling.

As a result of this conviction, on August 29, 2018, FDA sent Dr. Bhandari a notice by certified mail proposing to debar him for 3 years 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(b)(2)(B)(i)(I) of the FD&C Act, that Dr. Bhandari was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

The proposal offered Dr. Bhandari an opportunity to request a hearing, provided him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Bhandari received the proposal on September 4, 2018. Dr. Bhandari did not request a hearing within the timeframe prescribed by regulation and, therefore, has waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Dr. Bhandari has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing findings and in consideration of the factors described in section 306(c)(3) of the FD&C Act, Dr. Bhandari is debarred for a period of 3 years from providing services in any capacity to a person with an approved or pending drug product application under sections 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), effective (see **DATES**) (see sections 306(c)(1)(B), (c)(3), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(3), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Bhandari, in any capacity 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 Dr. Bhandari 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 applications submitted by or with the assistance of Dr. Bhandari during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Bhandari for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2018–N–1989 and sent to the Dockets Management Staff (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

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.

Dated: December 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27951 Filed 12–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Environmental Information Documentation (EID), OMB No. 0915–0324—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 25, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: HRSA Environmental Information and Documentation, OMB Number: 0915–0324—Revision.

Abstract: HRSA proposes revisions to the Environmental Information and Documentation (EID) checklist, which consists of information that the agency is required to obtain to comply with the National Environmental Policy Act of 1969 (NEPA). NEPA establishes the federal government's national policy for protection of the environment. The EID checklist must be completed and submitted by applicants for HRSA funds that plan to engage in construction or other projects that would potentially impact the environment. HRSA utilizes the checklist to ensure that decision-making processes are consistent with NEPA. The revisions will update some of the language in the checklist. For example, to better align with 45 CFR part 75, HRSA proposes to change the term ''grant'' to ''award'' and ''grantee'' to ''award recipient.''

Need and Proposed Use of the Information: Applicants for HRSA funds must provide information and assurance of compliance with NEPA on the EID checklist. This information is reviewed during the pre-award stage.

Likely Respondents: HRSA applicants applying for federal construction grants and cooperative agreements.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NEPA EID Checklist	1,500	1	1,500	1	1,500
Total	1,500		1,500		1,500

HRSA specifically requests comments on (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.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–28029 Filed 12–26–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) Announces the Following Advisory Committee Meeting

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Dates and Times: Wednesday, February 6, 2019: 9:00 a.m.–5:30 p.m.; Thursday, February 7, 2019: 8:30 a.m.–3:00 p.m.

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW, Rm. 505A, Washington, DC 20201.

Status: Open.

Purpose: At the February 6–7, 2019 meeting, the Committee will deliberate draft recommendations for the HHS Secretary, move forward on activities outlined in the NCVHS 2019 workplan, and hold discussions on several health data policy topics. Anticipated action items during this meeting include: (1) A letter to the Secretary regarding recommendations for revisions to principles for adoption of health terminology and vocabulary standards and new principles for curation and