nominations for non-voting industry representatives.

DATES: Nominations received on or before May 25, 2021 will be given first consideration for membership on the Blood Products Advisory Committee. Nominations received after May 25, 2021 will be considered for nomination to the Committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Nomination Portal: *https://www.accessdata.fda.gov/scripts/factrsportal/factrs/index.cfm.* Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/advisory-committees.*

FOR FURTHER INFORMATION CONTACT: Christina Vert, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993–0002, 240–402–8054, Fax: 301–595–1309, email: *BPAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members to fill upcoming vacancies on the Blood Products Advisory Committee.

I. General Description of the Committee Duties

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology that are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which FDA has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs (the Commissioner) of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses, and on the quality and relevance of FDA's research program that provides the scientific support for regulating these agents. The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act (FD&C Act) Medical Device Amendments of 1976. As such, the Committee recommends classification of devices subject to its review into regulatory categories; recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; recommends exemption of certain devices from the application of portions of the FD&C Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

II. Criteria for Voting Members

The Committee consists of a core of 17 voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, and email address if available and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06259 Filed 3–25–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–N–1671, FDA–2014–N–0386, FDA–2011–N–0076, FDA–2008–N–0312, FDA–2020–N–1677, FDA–2014–N–1072, and FDA–2019–N–5900]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB Control No.	Date approval expires
Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies	0910–0119	02/29/2024
Orphan Drugs	0910–0167	02/29/2024
Electronic Records: Electronic Signatures	0910–0303	02/29/2024
Extra Label Drug Use in Animals	0910–0325	02/29/2024
Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured from, Processed With, or Otherwise Containing, Material from Cattle	0910–0623	02/29/2024
Application for Participation in Food and Drug Administration Fellowship Programs	0910–0780	02/29/2024
Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion	0910–0894	02/29/2024

Dated: March 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06266 Filed 3–25–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2002]

Thomas J. Whalen: 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) debarring Thomas J. Whalen for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Whalen was convicted of multiple offenses; two of these are relevant to this debarment: One count of importation contrary of law-aiding and abetting and one count of healthcare fraud-aiding and abetting. The factual basis supporting Mr. Whalen's conviction is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Whalen was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of January 13, 2021 (30 days after receipt of the notice), Mr. Whalen had not responded. Mr. Whalen's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable March 26, 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, Division of Enforcement (ELEM–4029), 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(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance. On September 15, 2020, Mr. Whalen was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of Pennsylvania, when the court entered judgment against him for multiple offenses, two of which are relevant to this debarment: One count of importation contrary to law-aiding and abetting in violation of 18 U.S.C. 545 and 2, and one count of healthcare fraud-aiding and abetting in violation of 18 U.S.C. 1347 and 2.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for this conviction is as follows: As contained in the information in Mr. Whalen's case, filed on October 25, 2019, to which he pleaded guilty, he was a doctor of osteopathy in the Commonwealth of Pennsylvania and the State of Delaware. From about January 2014 to about March 2018, Mr. Whalen engaged in a scheme to defraud Medicare, the U.S. Office of Personnel Management (OPM), and the Independence Blue Cross insurance company (IBC). Specifically, he purchased, imported into the United States, and distributed misbranded and non-FDA-approved injectable versions of REMICADE (infliximab), SYNVISC/SYNVISC ONE (hyaluronan), ORENCIA (abatacept), PROLIA/XGEVA (denosumab), and BONIVA (ibandronate sodium). He then injected his patients with these non-FDA-approved versions of these medications. Mr. Whalen billed Medicare, OPM, and IBC for the provision of the FDA-approved versions of these products.

As a result of this conviction, FDA sent Mr. Whalen, by United Parcel Service, on December 11, 2020, a notice proposing to debar him for a 10-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Whalen's felony conviction for two felony counts under Federal law related to this debarment, specifically for one count of importation contrary to law-aiding and abetting and one count of healthcare fraud-aiding and abetting, was for conduct relating to the importation into the United States of any drug or controlled substance, because he illegally imported unapproved and misbranded drugs into the United States and then distributed those misbranded and unapproved drugs to consumers in the United States.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Whalen's offenses and concluded that each felony offense warranted the imposition of a 5-year period of debarment, for a total debarment period of 10 years. The proposal informed Mr. Whalen of the proposed debarment and offered him 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 request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Whalen received the proposal and notice of opportunity for