• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Sussan Paydar or Valerie Vashio, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 202–657–8533, *CBERVRBPAC@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On March 5, 2024, the committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2024 to 2025 influenza season.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at: *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before February 26, 2024, will be provided to the Committee. Comments received on or after February 26, 2024, and by March 4, 2024, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with their names, email addresses, and direct contact phone numbers of proposed participants, on or before 12 p.m. Eastern Time on Friday, February 16, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by 6 p.m. Wednesday, February 21, 2024.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Sussan Paydar or Valerie Vashio (See **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: February 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02709 Filed 2–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4717]

Brendon Gagne: 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 (the FD&C Act) debarring Brendon Gagne for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Gagne was convicted of one felony

count under Federal law for conspiracy to smuggle goods into the United States. The factual basis supporting Mr. Gagne's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Gagne 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 5, 2024 (30 days after receipt of the notice), Mr. Gagne had not responded. Mr. Gagne's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is effective February 9, 2024.

ADDRESSES: Any application by Mr. Gagne for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–4717. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240–402–8743, or *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 August 31, 2023, Mr. Gagne was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for Western District of Michigan when the court accepted his plea of guilty and entered judgment against him for two offenses, one of which was for conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545. The underlying facts supporting the conviction are as follows: As contained in the indictment from Mr. Gagne's case, filed on March 1, 2022, in the transcript from his guilty plea proceeding which was held on February 27, 2023, and from the Defendant's sentencing brief filed on August 15, 2023, beginning in or about 2018 and continuing until in or about October 2021, several individuals ran a website, *www.ExpressPCT.com,* which sold misbranded prescription drugs, as well as some Schedule III and Schedule IV controlled substances, in the United States without requiring a prescription. The drugs were manufactured overseas and then shipped in bulk to the United States to domestic redistributors. The packages did not declare their illicit contents and instead took steps to conceal their true nature. Once the packages entered the United States, the redistributors sent the bulk orders to second tier U.S.-based distributors who then finally shipped the drugs to the customers, making the purchasers think their drugs came from the United States and not from overseas. Part of Mr. Gagne's role in the scheme was to receive, repackage, and reship prescription drugs he received from other co-conspirators outside of the United States that were purchased by customers on the website *www.ExpressPCT.com.* In addition, Mr. Gagne recruited, managed and, using the profits from the sale of the misbranded prescription drugs, paid others engaged in the scheme who also received, repackaged, and reshipped prescription drugs they received from other co-conspirators outside of the United States.

As a result of this conviction, FDA sent Mr. Gagne, by certified mail, on November 30, 2023, a notice proposing to debar him for a 5-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. Gagne's felony conviction under Federal law for conspiracy to smuggle goods into the United States in violation of 18 U.S.C. 371 and 545, was

for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Gagne was involved in a scheme to illegally import and introduce misbranded prescription drugs into 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. Gagne's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Gagne 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. Gagne received the proposal and notice of opportunity for a hearing on December 6, 2023. Mr. Gagne failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived 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(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Brendon Gagne has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Gagne is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Gagne is a prohibited act.

Dated: February 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02706 Filed 2–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; HRSA Grantee Satisfaction Survey

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than March 11, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: HRSA Grantee Satisfaction Survey:

OMB No. 0906–0006—Revision.

Abstract: HRSA plans to survey HRSA grant recipients to better understand their opinions about HRSA's grants processes and to improve the way HRSA conducts business with them. This survey will focus on grantee customer satisfaction areas related to the grant life cycle, grantee relationships with HRSA staff (*e.g.,* Project Officers, Grants Management Officers), technical assistance received from HRSA Bureaus and Offices, availability of grant resources, and grantee access to guidance and instructional documents, etc. The seven grants management areas, which are directly related to the grants life cycle, are: Customer Service/Cooperation; Policies and Procedures; Pre-Award Phase; Award Phase; Reporting/Post-Award Administration; Technical Assistance; and Priorities for Improvement. Receiving this information from external customers will provide HRSA with a repository of information that will be incorporated into strategic efforts to improve grants management services and customer service.

HRSA revised the planned survey to reflect a change in the sampling methodology. In past survey administration cycles, HRSA sent a single survey to each organization and asked them to complete the survey for the award they had received from HRSA for the longest time period. This past approach did not allow for a range of program-specific feedback from HRSA grantees. In this survey administration cycle, HRSA will send the survey to each individual grant project director and ask them to complete the survey for a specific award. This new approach will enable HRSA to obtain more granular and actionable information regarding the full range of grant awards received by HRSA awardees.

Compared to the 60-day **Federal Register** notice, HRSA anticipates the number of potential survey respondents will increase from 3,690 to 7,813 due to the change in the sampling methodology. HRSA also anticipates an increase in the burden hours compared to the 60-day **Federal Register** notice, based on a reassessment of the time completion of the survey conducted during a pre-test. The adjusted average of completing the survey is 0.34 hours per response.

A 60-day notice for this information collection was published in the **Federal Register** on March 10, 2023, Vol. 88, No. 47; pp. 15053. There were no public comments.

Need and Proposed Use of the Information: The HRSA Grantee Satisfaction Survey will provide meaningful and relevant results to agency decision-makers about various customer satisfaction domains (*e.g.,* efficiency, timeliness, usefulness, responsiveness, quality of and overall satisfaction with HRSA project officers, products and services). The information collected will assist HRSA in its efforts to gauge, understand and respond to the needs and concerns of its customers, especially as they relate to the aforementioned areas. The survey results will provide HRSA with concrete indicators regarding the best areas in which to dedicate resources to improve