August 29, 2016, 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. Manookian was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. FDA determined that Mr. Manookian's felony convictions were related to the regulation of drug products because the conduct underlying his convictions undermined FDA's regulatory oversight over drug products marketed in the United States—Mr. Manookian knowingly sold unapproved drugs and put patients at risk. The proposal also offered Mr. Manookian 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. The proposal was received on September 2, 2016. Mr. Manookian did not request a hearing 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 Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Edward Manookian has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Section 306(c)(2)(A)(ii) of the FD&C Act requires that Mr. Manookian's debarment be permanent.

As a result of the foregoing finding, Edward Manookian is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application 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), effective (see **DATES**) (see sections 201(dd) (21 U.S.C. 321(dd), 306(c)(1)(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 the services of Edward Manookian, 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 Mr. Manookian 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 from Edward Manookian during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Manookian for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2015–N–4169 and sent to the Division of Dockets Management (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.

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

Dated: November 7, 2016.

Armando Zamora,

Deputy Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs.

[FR Doc. 2016–27244 Filed 11–10–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0144]

Voluntary Qualified Importer Program; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''FDA's Voluntary Qualified Importer Program.'' The guidance describes the Voluntary Qualified Importer Program (VQIP), which provides for expedited review and importation of food offered for importation by importers who voluntarily agree to participate in the program. The guidance describes the eligibility criteria for, and benefits of, participation in VQIP. The guidance also provides information on submitting an application for VQIP participation, obtaining a facility certification for the foreign supplier of a food imported under VQIP, the VQIP user fee, conditions that might result in the revocation of VQIP eligibility, and criteria for reinstatement of eligibility.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed below (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2011–N–0144 for ''FDA's Voluntary Qualified Importer Program.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets

Management between 9 a.m. and 4 p.m., Monday through Friday.

• *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.'' The Agency 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to 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 this 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for a single hard copy of the guidance to the Office of Enforcement and Import Operations (ELEM–3108), Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Office of Enforcement and Import Operations (ELEM–3108), Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, 301–796–0356.

Regarding the information collection: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 11601 Landsdown St., 10A–12M, North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 302 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 806, Voluntary Qualified Importer Program (21 U.S.C. 384b). Section 806(a)(1) of the FD&C Act directs FDA to establish a voluntary program for the expedited review and importation of food, and to establish a process for the issuance of a facility certification to accompany food offered for importation by importers participating in VQIP. Section 806(a)(2) of the FD&C Act directs FDA to issue a guidance document related to participation in, revocation of such participation in, reinstatement in, and compliance with VQIP.

We are announcing the availability of a guidance for industry entitled ''FDA's Voluntary Qualified Importer Program.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of June 5, 2015 (80 FR 32136), we made available a draft guidance for industry on VQIP for importers of human or animal food and gave interested parties an opportunity to submit comments by August 19, 2015, for us to consider before beginning work on the final version of the guidance. We received numerous comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include:

• Clarifying that, during the VQIP fiscal year, a VQIP importer may add additional food from a foreign supplier from which the importer already imports food under VQIP;

• clarifying that VQIP applicants will not be required to upload food labels for foods included in the VQIP application, but FDA may request a copy of food labels for the foods included in the application to determine if there are labeling violations relating to the risk of the food during a VQIP inspection or audit examinations;

• providing examples of how to ensure that the Foreign Supplier Verification Program (FSVP) or the Hazard Analysis and Critical Control Point (HACCP) importer of the food (when it is not the VQIP applicant) is in compliance with the applicable FSVP or HACCP regulations; and

• revising the '3-year import history' eligibility criteria to provide for use of shared importation history of previous or parent companies.

We also made editorial changes and changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated June 2015.

VQIP begins on January 1, 2018, which is the first date FDA will begin accepting applications to participate in VQIP for the fiscal year 2019 beginning October 1, 2018. We encourage food importers with robust supplier verification programs to apply for participation in VQIP. We anticipate that VQIP will allow FDA to focus its resources on food shipments that pose a higher risk to public health and will facilitate risk-based admissibility practices. We anticipate that we will approve approximately 200 applications for the first year of the program. We established this limit based on consideration of the demands on Agency resources necessary to establish and implement VQIP. We will review applications in the order that we receive them.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, in the **Federal Register** of June 5, 2015, we gave interested persons 60 days to comment on the information collection provisions in the draft guidance (80 FR 32136 at 32138).

Currently FDA is finalizing the VQIP application and will be submitting the proposed collection for OMB review and clearance under 44 U.S.C. 3507. 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. FDA is issuing this final guidance subject to OMB approval of the collection of information. Before the Agency begins collecting information for the VQIP program, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the guidance.

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information regarding food labeling have been approved under OMB control number 0910–0381; the collections of information regarding Low Acid Canned Food have been approved under OMB control number 0910–0037; the collections of information regarding Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications have been approved under OMB control number 0910–0750; the collections of information regarding Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food have been approved under OMB control number 0910–0751; the collections of information regarding Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals have been approved under OMB control number 0910–0789; the collections of information regarding the Foreign Supplier Verification Program have been approved under OMB control number 0910–0752; the collections of information regarding the Sanitary Transportation of Human and Animal Food have been approved under OMB control number 0910–0773; and the collections of information regarding Focused Mitigation Strategies to Protect Food Against Intentional Adulteration have been approved under OMB control number 0910–0812.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/RegulatoryInformation/Guidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

IV. Other Issues for Consideration

FSMA directs FDA to collect user fees to fund VQIP. Consistent with section 743(b)(2)(B)(iii) of the FD&C Act, we set forth a proposed set of guidelines in consideration of the burden of user fee amounts on small businesses in the **Federal Register** of June 5, 2015 (80 FR 32136), which also announced the draft guidance for industry on VQIP. We are considering comments we received on the VQIP user fee. We will publish the actual fee in a **Federal Register** notice in accordance with section 743(b)(1) of the FD&C Act prior to the fiscal year when we begin program benefits.

Dated: November 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27252 Filed 11–10–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0579]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Deviations in Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 (the PRA).

DATES: Fax written comments on the collection of information by December 14, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0458. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing; Forms FDA 3486 and 3486A.

OMB Control Number 0910–0458—Extension

Under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), all biological products, including human blood and blood components, offered for sale in interstate commerce must be licensed and meet standards, including those prescribed in FDA regulations, designed to ensure the continued safety, purity, and potency of such products. In addition under section 361 of the PHS Act (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States or possessions. Further, section 501 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351) provides that drugs and devices (including human blood and blood components) are adulterated if they do not conform with current good manufacturing practice (CGMP) assuring that they meet the requirements of the FD&C Act. Establishments manufacturing biological products, including human blood and blood components, must comply with the applicable CGMP regulations (21 CFR parts 211, 606, and 820)) and current good tissue practice (CGTP) regulations (part 1271 (21 CFR part 1271)) as appropriate. FDA regards biological product deviation (BPD) reporting and human cells, tissues, and cellular and tissue-based product (HCT/P) deviation reporting to be an essential tool in its directive to protect public health by establishing and maintaining surveillance programs that provide timely and useful information.

Section 600.14 (21 CFR 600.14), in brief, requires the manufacturer who holds the biological product license, for other than human blood and blood components, and who had control over a distributed product when the deviation occurred, to report to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drugs Evaluation and Research (CDER) as soon as possible but at a date not to exceed 45 calendar days after acquiring information reasonably suggesting that a