Considering all applicable factors under 306(c)(3) of the FD&C Act, OSI concurs with ORA's proposal that a 5-year period of debarment for each offense is warranted. On this record, OSI finds that the nature and seriousness of the offenses and the nature and extent of Meunerie Sawyerville management's participation in the offenses are factors weighing heavily in favor of debarment. For the reasons already discussed, even assuming Meunerie Sawyerville has discontinued using monensin in its operations, OSI finds that operational change insufficient under section 306(c)(3)(D) to demonstrate correction of the causes of these offenses and to provide reasonable assurances that the offenses will not recur. Further, even after taking into account Meunerie Sawyerville's guilty plea under section 306(c)(3)(C), OSI finds that Meunerie Sawyerville's conduct related to this consideration weighs in favor of debarment. Although Meunerie Sawyerville's lack of a prior conviction under 306(c)(3)(F) is a factor weighing against debarment, this consideration is substantially outweighed by the nature and seriousness of the offenses, the nature and extent of management's participation in the offenses, and the nature and extent of voluntary steps to mitigate the impact of the offenses on the public. Therefore, considering all of these factors together and the record as a whole, OSI finds that a 5-year period of debarment is warranted for each offense.

Therefore, the Director of OSI, under section 306(b)(3)(A) of the FD&C Act and under authority delegated to him by the Commissioner of Food and Drugs, finds that Meunerie Sawyerville has been convicted of a felony for conduct relating to the importation of food into the United States. FDA has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate for each of these felony offenses. These periods will run concurrently under section 306(c)(2)(A). As a result of the foregoing findings, Meunerie Sawyerville is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, applicable (see **DATES**). Under section 301(cc) of the FD&C Act, the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Meunerie Sawyerville is a prohibited act.

Dated: February 26, 2018.

George M. Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2018–04195 Filed 2–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0313]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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.

DATES: Fax written comments on the collection of information by April 2, 2018.

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 0910–0787. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings With the Office of Orphan Products Development

OMB Control Number 0910–0787—Extension

This information collection supports Agency guidance regarding staff meetings with the Office of Orphan Products Development (OOPD). Each year, the OOPD staff participates in meetings with stakeholders who seek guidance or clarification relating to orphan drug or humanitarian use device (HUD) designation requests, OOPD grant programs, or other rare disease issues. These meetings can be ''informal'' or ''formal'' and help build a common understanding on FDA's thoughts on orphan products, which may include drugs, biological products, devices, or medical foods for a rare disease or condition. These meetings may represent critical points in the orphan product development process and may even have an impact on the eventual availability of products for patients with rare diseases and conditions. It is important that these meetings be scheduled within a reasonable time, conducted effectively, and documented where appropriate.

Topics addressed in this guidance include: (1) Clarification of what constitutes an ''informal'' or ''formal'' meeting, (2) program areas within OOPD that may be affected by this draft guidance, (3) procedures for requesting and scheduling meetings with OOPD, (4) description of what constitutes a meeting package, and (5) procedures for the conduct and documentation of meetings with OOPD. This guidance provides consistent procedures to promote well-managed meetings between OOPD and stakeholders.

Burden estimate. Table 1 provides an estimate of the annual reporting burden associated with the recommendations found in the guidance.

Request for a meeting. Based upon information collected from OOPD program areas, approximately 2,332 informal and 51 formal meetings were requested with OOPD in fiscal year (FY) 2016 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of meeting requests and stakeholders will remain the same or will slightly increase and therefore estimates the total number of meeting

requests will be 2,383 annually (2,332 informal and 51 formal meetings). The hours per response, which is the estimated number of hours that a stakeholder would spend preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be approximately 3 hours for informal meetings and approximately 10 hours for formal meetings. Based on FDA's experience, the Agency expects that it will take stakeholders this amount of time to gather and copy brief statements about the product and a description of the purpose and details of the meeting. Therefore, the Agency estimates that stakeholders will spend 7,506 hours per year (6,996 hours for informal meetings and 510 hours for formal meetings) preparing meeting requests to OOPD regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues.

Meeting packages. Based upon information collected from OOPD program areas, OOPD held approximately 51 formal meetings in FY 2016 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of formal meetings, and therefore meeting packages, will remain the same; thus, the Agency estimates that the total responses will be 51 annually. As stated previously, it is current practice for stakeholders to submit meeting packages to the Agency in advance of any such formal meeting. The hours per response, which is the estimated number of hours that a stakeholder would spend preparing the meeting package in accordance with this guidance, is estimated to be approximately 18 hours. Based on FDA's experience, the Agency expects it will take stakeholders this amount of time to gather and copy brief statements about the product, a description of details for the anticipated meeting, and data and information that generally would already have been compiled for submission to the Agency. Therefore, the Agency estimates that stakeholders will spend 918 hours per year submitting meeting packages to the Agency prior to a formal meeting regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues.

Draft meeting minutes. Based upon information collected from OOPD program areas, OOPD received approximately 51 draft meeting minutes for formal meetings and 23 draft meeting minutes for informal meetings in FY 2016 regarding orphan drug designation requests, HUD designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related issues. FDA anticipates that the number of stakeholders submitting draft meeting minutes will likely remain the same; thus, the Agency estimates that the total number of respondents will be 74 annually. As stated previously, it is current practice for stakeholders to submit draft meeting minutes to the Agency after all formal meetings and certain informal meetings. The hours per response, which is the estimated number of hours that a stakeholder would spend preparing draft meeting minutes in accordance with the recommendations of the guidance, is estimated to be approximately 8 hours. Based on FDA's experience, the Agency expects it will take stakeholders this amount of time to summarize the meeting discussion points, agreements, disagreements, and action items. Therefore, the Agency estimates that stakeholders will spend 592 hours per year submitting draft meeting minutes to the Agency documenting the meeting outcomes, agreements, disagreements, and action items as followup to all formal and certain informal meetings.

In the **Federal Register** of November 17, 2017 (82 FR 54357), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA therefore estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Meeting requests, packages and minutes	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting requests (informal)	2,332	1	2,332	3	6,996
Meeting requests (formal)	51	1	51	10	510
Meeting packages	51	1	51	18	918
Meeting minutes	74	1	74	8	592
Total					9,016

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Since the last OMB approval, we have increased our estimate by 832 hours and 229 respondents in parallel to an increase in overall orphan drug designation submissions and the corresponding meeting requests to the OOPD.

Dated: February 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04153 Filed 2–28–18; 8:45 am]

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