Review Improvement Act of 1982 amended Title XI of the Social Security Act to create the Utilization and Quality Control Peer Review Organization (PRO) program which replaces the Professional Standards Review Organization (PSRO) program and streamlines peer review activities. The term PRO has been renamed Quality Improvement Organization (QIO). This information collection describes the review functions to be performed by the QIO. It outlines relationships among QIOs, providers, practitioners, beneficiaries, intermediaries, and carriers. *Form Number:* CMS–R–71 (OMB Control Number: 0938–0445); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 6,939; *Total Annual Responses:* 44,015; *Total Annual Hours:* 100,065. (For policy questions regarding this collection contact Tennille Coombs at 410–786–3472.)

Dated: December 9, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–30024 Filed 12–13–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–N–2016–4198]

Public Meeting on Patient-Focused Drug Development for Sarcopenia; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on ''Patient-Focused Drug Development for Sarcopenia.'' Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of sarcopenia on daily life as well as patient views on treatment approaches for sarcopenia.

DATES: The public meeting will be held on April 6, 2017, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by March 27, 2017 (see **SUPPLEMENTARY INFORMATION** for instructions). Public comments will be accepted through June 6, 2017. See the **ADDRESSES** section for information about submitting comments to the public docket.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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 (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–2016–N–4198 for ''Public Meeting on Patient-Focused Drug Development for Sarcopenia; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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 *https://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 *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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FDA will post the agenda approximately 5 days before the meeting

at: *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm527587.htm.*

FOR FURTHER INFORMATION CONTACT: Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 240–402–6525, FAX: 301–847–8443, *Meghana.Chalasani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected sarcopenia as the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patient perspectives on the severity of a disease and the available therapies for that condition. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments that are part of the reauthorization of the PDUFA under Title I of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144). The full set of performance commitments is available at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA committed to obtain the patient perspective on at least 20 disease areas during the course of PDUFA V. For each disease area, the Agency is conducting a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On April 11, 2013, FDA published a notice in the **Federal Register** (78 FR 21613) announcing the disease areas for meetings in fiscal years (FYs) 2013–2015, the first 3 years of the 5-year PDUFA V time frame. The Agency used several criteria outlined in that notice to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. FDA initiated a second public process for determining the disease areas for FY 2016–2017, and published a notice in the **Federal Register** on July 2, 2015 (80 FR 38216), announcing the selection of eight disease areas. More information, including the list of disease areas and a general schedule of meetings, is posted at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.*

II. Public Meeting Information

As part of Patient-Focused Drug Development, FDA will obtain patient and patient stakeholder input on the symptoms of sarcopenia that matter most to patients and on current approaches to treating sarcopenia. Sarcopenia is a condition characterized by loss of muscle mass and loss of muscle function or strength that occurs with age. While there is currently no cure, treatments for sarcopenia are primarily non-drug therapies including exercise and nutrition. FDA is interested in the perspectives of patients with sarcopenia on (1) symptoms and the daily impacts of their condition, (2) current approaches to treatment, and (3) decision factors taken into account when selecting a treatment.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**).

Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

(1) Of all the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life? (Examples may include difficulty walking, feeling unsteady and falling frequently, having a decreased level of activity, etc.)

(2) Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include participation in social activities, household chores, daily hygiene, etc.)

(3) How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?

(4) How have your condition and its symptoms changed over time?

(a) Would you define your condition today as being well managed?

(5) What worries you most about your condition?

Topic 2: Patients' Perspectives on Current Approaches to Treatment

(1) What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies such as diet modification.)

(a) What specific symptoms do your treatments address?

(b) How has your treatment regimen changed over time, and why?

(2) How well does your current treatment regimen control your condition?

(a) How well do your treatments address specific activities that are important to you in your daily life?

(b) How well have these treatments worked for you as your condition has changed over time?

(3) What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include going to the hospital or clinic for treatment, time devoted to treatment, etc.)

(4) What specific things would you look for in an ideal treatment for your condition?

(a) What would you consider to be a meaningful improvement (for example, symptom improvements or functional improvements) in your condition that a treatment could provide?

III. Meeting Attendance and Participation

If you wish to attend this meeting, visit *https://sarcopeniapfdd.eventbrite.com.* Please register by March 27, 2017. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability.

If you need special accommodations because of a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by March 20, 2017. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A link to the transcript will also be available on the Internet at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm527587.htm.*

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29998 Filed 12–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0375; FDA–2013–N–0370; FDA–2013–N–0134; FDA–2009–N–0511; FDA–1997–N–0020; FDA–2011–N–0902; FDA–2013–N–0662; FDA–2013–N–0450; FDA–2012–N–0477; FDA–2013–N–0519]

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: 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: 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 *http://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
Agreement for Shipments of Devices for Sterilization	0910–0131	9/30/2019
Export of Medical Devices—Foreign Letters of Approval	0910–0264	9/30/2019
Mammography Facilities, Standards, and Lay Summaries for Patients	0910–0309	9/30/2019
Medicated Fee Mill License Application	0910–0337	9/30/2019
Substances Generally Recognized as Safe: Notification Procedure	0910–0342	9/30/2019
Prescription Drug Product Labeling; Medication Guide Requirements	0910–0393	9/30/2019
Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed	0910–0513	9/30/2016
Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed	0910–0339	10/31/2019
Investigational Device Exemptions Reports and Records—21 CFR 812	0910–0078	11/30/2019
Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the FDA Electronic Submission Gateway	0910–0454	11/30/2019

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30035 Filed 12–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4119]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2017 fee rate for accreditation bodies applying to be recognized in the third-party certification program that is authorized by the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA).

FOR FURTHER INFORMATION CONTACT: Sylvia Kim, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3212, Silver Spring, MD 20993, 301–796–7599.

DATES: This fee is effective January 13, 2017, and will remain in effect through September 30, 2017.

SUPPLEMENTARY INFORMATION:

I. Background

Section 307 of FSMA, Accreditation of Third-Party Auditors, amends the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs us to establish a new program for accreditation of third-party certification bodies [1] conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign

[1] For the reasons explained in the third-party certification final rule (80 FR74570 at 74578–74579, November 27, 2015), and for consistency with the implementing regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term ''third-party certification body'' rather than the term ''third-party auditor'' used in section 808(a)(3) of the FD&C Act.