1552, Silver Spring, MD 20993, 301–796–5290, *Natasha.Facey@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 Agency's Web site at *http://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.

Agenda: On November 14, 2014, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the AcrySof® IQ ReSTOR® Multifocal Toric Posterior Chamber Intraocular Lens submitted by applicant Alcon Laboratories, Inc. This intraocular lens combines the optical properties of a +3 diopter multifocal intraocular lens with the optical properties of a toric intraocular lens. The proposed indication for use is: The AcrySof® IQ ReSTOR® Multifocal Toric Posterior Chamber Intraocular Lens (IOL) are intended for primary implantation for the visual correction of aphakia and pre-existing astigmatism secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision, reduction of residual refractive cylinder, and increased spectacle independence. The lens is intended to be placed in the capsular bag.

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 Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 10, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 30, 2014. 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 November 3, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark at *James.Clark@fda.hhs.gov* or 301–796–5293 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://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. app. 2).

Date: September 22, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–22905 Filed 9–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1413]

Patient-Focused Drug Development Public Meeting and Scientific Workshop on Female Sexual Dysfunction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and scientific workshop, both of which will provide an opportunity for public comment on the topic of Female Sexual Interest/Arousal Disorder (FSIAD), the most common form of female sexual dysfunction. FSIAD is a diagnosis that combines two previously distinct disorders—hypoactive sexual desire disorder (HSDD) and female sexual arousal disorder (FSAD). The public meeting will take place on October 27, 2014, and is part of FDA's Patient-Focused Drug Development performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). At this meeting, FDA will obtain patients' perspectives on the impact that FSIAD (or a prior diagnosis of HSDD or FSAD) has on their daily lives, as well as their perspectives on the available therapies for these conditions. The scientific workshop will take place on October 28, 2014, and will provide an opportunity for FDA to seek input from experts on scientific issues important to the clinical development of drug products intended to treat FSIAD.

DATES: The meeting will be held on October 27, 2014, from 12 p.m. to 5 p.m. and the workshop will be held on October 28, 2014, from 8 a.m. to 5 p.m. Registration to attend either the meeting or the workshop must be received by October 17, 2014. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for either the meeting or the workshop. Submit electronic or written comments by December 29, 2014.

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

Submit electronic comments to *www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the

docket number found in brackets in the heading of this document. Please indicate whether the comments are relevant to the October 27 meeting or the October 28 workshop. FDA will post the agenda approximately 5 days before the meeting at *http://www.fda.gov/Drugs/NewsEvents/ucm401167.htm.*

FOR FURTHER INFORMATION CONTACT:

For questions regarding the October 27 Patient-Focused Drug Development meeting: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1144, Silver Spring, MD 20993, 301–796–0684, FAX: 301–847–8443, *Pujita.Vaidya@fda.hhs.gov.*

For questions regarding the October 28 scientific workshop: Charlene Williamson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5332, Silver Spring, MD 20993, 301–796–1025, *Charlene.Williamson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected female sexual dysfunction as the focus of a meeting under Patient-Focused Drug Development initiative that involves obtaining a better understanding of patients' perspectives on the severity of the disease and the available therapies for the condition. This Patient-Focused Drug Development meeting is being conducted to fulfill FDA's performance commitments made as part of the authorization of PDUFA V under Title I of the Food and Drug Safety and Innovation Act (Pub. L. 112–144). The full set of performance commitments is available on the FDA Web site at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA has committed to obtain the patient perspective in 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct 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 community, 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 through 2015, the first 3 years of the 5-year PDUFA V time frame. To develop the list of disease areas, the Agency used several criteria that were outlined in the April 11 notice. The Agency obtained public comment on these criteria and potential disease areas through a notice for public comment published in the **Federal Register** on September 24, 2012 (77 FR 58849), and through a public meeting held on October 25, 2012. In selecting the disease areas, FDA carefully considered the public comments received and the perspectives of its review divisions. By the end of FY 2015, FDA will initiate another public process to determine the disease areas for FYs 2016 through 2017. 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 and Workshop Information

A. Purpose and Scope of the Meeting and Workshop

On October 27, 2014, as part of Patient-Focused Drug Development, FDA will obtain patient and patient stakeholder input on symptoms of female sexual dysfunction that matter most to patients and on current approaches to treating female sexual dysfunction. The most common form of female sexual dysfunction, FSIAD, refers to absent or reduced sexual interest/arousal that causes clinically significant distress and is not caused by another condition (such as another medical disorder or the effects of medications). There are no FDA-approved drug therapies to treat FSIAD. FDA is committed to working with all stakeholders to foster the development of safe and effective therapies for affected women.

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

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

- Have you ever received a diagnosis from a healthcare provider of sexual interest/arousal disorder, hypoactive sexual desire disorder, or sexual arousal disorder?
- How was the diagnosis made? For example, what type of healthcare provider made the diagnosis? Were any tests or questionnaires used to help make the diagnosis?
- Of all the symptoms that you experience because of your condition, which 1 to 3 symptoms have the most significant impact on your life? Please describe each symptom in detail, including how this symptom specifically affects your sexual experiences.
- Do your symptoms wax and wane over time? For example, do you have better days and worse days? If your symptoms wax and wane, please answer the following questions:
- Which symptoms vary the most, and in what ways?
- How do your symptoms and their negative impacts on your sexual experiences compare between your ''best days'' and your ''worst days''?
- Do the changes in your symptoms typically happen over a period of minutes, hours, days, weeks, or months?
- If you were asked today to accurately rate how good or how bad your symptoms have been over time, would you be able to accurately remember how your symptoms felt one day ago? Over the past 3 days? Over the past week? Over the past 2 weeks? Over the past 3 weeks? Over the past month?
- Is there anything else that you believe makes your symptoms better? Is there anything that you believe makes your symptoms worse? For example, menstruation, stress, etc.
- Overall, have you experienced your condition and its symptoms getting progressively worse, improving, or remaining stable over the past few years?
- What worries you most about your condition?

2. Topic 2: Patient perspectives on Current Approaches To Treat FSIAD

- What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, physical or other therapies, support groups, and lifestyle changes.)
- How well do your current treatments specifically treat the most significant symptoms of your condition?
- How well have your treatments improved your sexual experience?
- How has your treatment regimen changed over time, and why?
- Are there any downsides to the treatments you have used? (Examples of downsides may include bothersome

side effects, difficulty identifying appropriate healthcare providers, etc.)

- What specific things would you look for in an ideal treatment for your condition? For example, which symptom would you most like a treatment to target and what would you consider to be a meaningful improvement in this symptom?

The scientific workshop on October 28, 2014 will include a discussion of scientific challenges related to:

- Diagnosis of the condition for clinical trials and in clinical practice and
- ensuring valid patient-reported outcome measures for the key efficacy endpoints used in clinical trials.

B. Meeting and Workshop Attendance and Participation

If you wish to attend the Patient-Focused Drug Development meeting or scientific workshop, visit *http://fsdpatientfocused.eventbrite.com.* Please register for either the meeting or workshop by October 17, 2014. If you are unable to attend the meeting or workshop in person, you can register to view a live Webcast. You will be asked to indicate in your registration whether 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 meetings will be based on space availability. If you need special accommodations because of disability, please contact Pujita Vaidya or Charlene Williamson (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 during the October 27 meeting must indicate in their registration which topic(s) they wish to address. These patients also must send a brief summary of responses to the topic questions by October 3, 2014, to *PatientFocused@fda.hhs.gov.* 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.

FDA will hold an open public comment period during the October 27 meeting and the October 28 workshop to give the public an opportunity to comment. Registration for open public comment will occur at the registration desk on the day of the meeting and workshop on a first-come, first-serve basis.

III. Comments

Regardless of attendance at the Patient-Focused Drug Development meeting, you can submit electronic or written comments, including responses to the questions pertaining to Topics 1 and 2, to the public docket (see **ADDRESSES**) by December 29, 2014. Please indicate whether the comments are relevant to the October 27 meeting or the October 28 workshop. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Transcripts

As soon as a transcript is available, FDA will post it at *http://www.fda.gov/Drugs/NewsEvents/ucm401167.htm.*

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22983 Filed 9–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on August 1, 2014, through August 31, 2014. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.