effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act (21 U.S.C. 360e(g)). The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2014, through June 30, 2014. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2014, THROUGH JUNE 30, 2014

PMA No., Docket No.	Applicant	Trade name	Approval date
P130016, FDA–2014–M–0327.	Cochlear Americas	Nucleus® Hybrid™ L24 Cochlear Implant System	March 20, 2014.
P120020, FDA–2014–M–0434.	Abbott Vascular (IDEV Technologies, Inc.).	SUPERA® Peripheral Stent System	March 28, 2014.
P010015/S205, FDA–2014–M–0553.	Medtronic, Inc	Cardiac Resynchronization Therapy Pacemaker (CRT–P) Devices.	April 10, 2014.
P010031/S381, FDA–2014–M–0553.	Medtronic, Inc	Cardiac Resynchronization Therapy Defibrillator (CRT–D) Devices.	April 10, 2014.
P100020/S008, FDA–2014–M–0552.	Roche Molecular Systems, Inc	cobas® HPV Test	April 24, 2014.
P130008, FDA–2014–M–0690.	Inspire Medical Systems, Inc	Inspire Upper Airway Stimulation (UAS) system	April 30, 2014.
P110005, FDA–2014–M–0691.	IBSA Institut Biochimique SA	Gel-Syn™ Sinovial (Sodium Hyaluronate 0.8%)	May 9, 2014.
P110041, FDA–2014–M–0692.	Siemens Healthcare Diagnostics	ADVIA Centaur® HBsAgII, ADVIA Centaur® HBsAg Confirmatory and ADVIA Centaur® HBsAg Quality Control Material.	May 16, 2014.
P110027, FDA–2014–M–0726.	QIAGEN Manchester Ltd	therascreen® KRAS RGQ PCR Kit	May 23, 2014.
P100045, FDA–2014–M–0727.	CardioMEMS, Inc	CardioMEMS™ HF System	May 28, 2014.
P130027, FDA–2014–M–0866.	QIAGEN, Inc	artus® CMV RGQ MDx Kit	June 2, 2014.
P040024/S072, FDA–2014–M–0872.	Valeant Pharmaceuticals North America LLC/Medicis.	Restylane Silk Injectable Gel	June 13, 2014.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: September 23, 2014

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22987 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–0001]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 14, 2014, from 8 a.m. to 6 p.m.

Location: Hilton Washington, DC North/Gaithersburg, Montgomery Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.

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