Food and Drug Administration Staff'' are approved under OMB control number 0910–0756.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. 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.*

Dated: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02722 Filed 2–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–M–0867, FDA–2014–M–0874, FDA–2014–M–0875, FDA–2014–M–1060, FDA–2014–M–1064, FDA–2014–M–1113, FDA–2014–M–1114, FDA–2014–M–1193, FDA–2014–M–1265, FDA–2014–M–1279, and FDA–2014–M–1280]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and 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. 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 July 1, 2014, through September 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 JULY 1, 2014, THROUGH SEPTEMBER 30, 2014

PMA No., Docket No.	Applicant	Trade name	Approval date
P130021/S002, FDA–2014–M–0867	Medtronic CoreValve LLC	Medtronic CoreValve™ System (MCS)	June 12, 2014.
P130009, FDA–2014–M–0874	Edwards Lifesciences, LLC	Edwards SAPIEN XT™ Transcatheter Heart Valve and Accessories.	June 16, 2014.
P130029, FDA–2014–M–0875	Bard Peripheral Vascular, Inc	Fluency® Plus Endovascular Stent Graft.	June 17, 2014.
P130011, FDA–2014–M–1064	Sorin Group Canada, Inc	Freedom SOLO Stentless Heart Valve and SOLO Smart Heart Valve.	June 24, 2014.
P130030, FDA–2014–M–1060	Boston Scientific Corp	REBEL™ Platinum Chromium Coronary Stent System (Monorail™ and Over-The-Wire).	June 27, 2014.
P090029, FDA–2014–M–1113	Medtronic Sofamor Danek USA, Inc	Prestige® LP Cervical Disc	July 24, 2014.
H130005, FDA–2014–M–1114	MicroVention, Inc	Low-Profile Visualized Intraluminal Support Device (LVIS and LVIS Jr.).	July 25, 2014.
P130017, FDA–2014–M–1193	Exact Sciences, Inc	COLOGUARD™	August 11, 2014.
H120003, FDA–2014–M–1265	XVIVO Perfusion, Inc	XVIVO Perfusion System (XPS™) with STEEN Solution™ Perfusate.	August 12, 2014.
H130004, FDA–2014–M–1280	Plexision, Inc	Pleximmune™	August 26, 2014.
P130020, FDA–2014–M–1279	GE Healthcare	SenoClaire	August 26, 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: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02783 Filed 2–10–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0244]

Patient-Focused Drug Development for Functional Gastrointestinal Disorders; Public Meeting; 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 functional gastrointestinal (GI) disorders, including irritable bowel syndrome, gastroparesis, chronic persistent symptomatic gastroesophageal reflux despite standard therapeutic interventions, and chronic idiopathic constipation. 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 functional GI disorders on daily life and patient views on treatment approaches.

DATES: The public meeting will be held on May 11, 2015, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by May 1, 2015 (see **SUPPLEMENTARY INFORMATION** for instructions). Submit electronic or written comments to the public docket by July 13, 2015.

ADDRESSES: The 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. Participants must enter through Building 1 and undergo security screening. For more information on parking and security procedures, 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, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm430885.htm.*

FOR FURTHER INFORMATION CONTACT: Pegah Mariani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 240–402–4513, FAX: 301–847–8443, *Sayyedeh.Mariani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected functional GI disorders 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 (FDASIA) (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 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 communities, and other interested stakeholders.

On April 11, 2013, FDA published a document 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 timeframe. The Agency used several criteria outlined in that document 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 has initiated a second public process for determining the disease areas for FY 2016–2017. 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 Information

A. Purpose and Scope of the Meeting

The purpose of this Patient-Focused Drug Development meeting is to obtain input on the symptoms and other impacts of functional GI disorders, such as irritable bowel syndrome, gastroparesis, chronic persistent symptomatic gastroesophageal reflux despite standard therapeutic interventions, and chronic idiopathic constipation, that matter most to patients, as well as perspectives on current approaches to treating these conditions. Functional GI disorders are common disorders that are characterized by persistent and recurring GI symptoms and occur as a result of abnormal functioning of the GI tract. These disorders are not caused by structural abnormalities, thus routine medical tests may be normal, and diagnosis is based primarily on symptoms. Functional GI disorders can affect any part of the GI tract, including the esophagus, bile duct, and intestines. Treatment for functional GI disorders focuses on management of different symptoms over a period of time. Treatments may include dietary management as well as over-the-counter and prescription medications (*e.g.,* antispasmodics, pro-motility agents, antidiarrheals, and antidepressants). In addition, psychological treatments, such as relaxation therapy or cognitive behavioral therapy, may help manage the symptoms of functional GI disorders.

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