electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA Center for Devices and Radiological Health, Letters to Industry Page, ''Letter to Manufacturers of Enteral Feeding Tubes,'' (*http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM218631.pdf*).

Dated: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02802 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–D–0288]

Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices.'' This leap frog guidance document was developed to notify manufacturers of the recommended non-clinical and clinical studies to support a premarket approval application (PMA) for implantable MIGS devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 12, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michelle Tarver, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 2504, Silver Spring, MD 20993–0002, 301–796–5620.

SUPPLEMENTARY INFORMATION:

I. Background

When finalized, this draft guidance document will recommend non-clinical and clinical studies to support a PMA for implantable MIGS devices. Glaucoma is a progressive condition that damages the optic nerve of the eye, is associated with elevated intraocular pressure, and leads to irreversible vision loss. It is the second leading cause of visual disability and blindness in the world, with 1 in 40 adults over 40 years of age suffering from glaucoma having some visual loss. Current surgical treatments are aimed at reducing intraocular pressure (IOP) and often reserved for moderate to severe disease. During the past decade, novel medical devices, called MIGS devices, have emerged. These devices are designed to treat less severe glaucoma by enhancing physiological aqueous outflow with an approach that causes minimal ocular trauma.

This draft guidance is a leap-frog guidance; leap frog guidances are intended to serve as a mechanism by which the Agency can share initial thoughts regarding the content of premarket submissions for emerging technologies and new clinical applications that are likely to be of public health importance very early in product development, generally before FDA has even received any such submissions. This leap-frog guidance represents the Agency's initial thinking and our recommendations may change as more information becomes available. The Agency strongly encourages manufacturers to engage with the Center for Devices and Radiological Health (CDRH) through the Pre-Submission process to obtain more detailed feedback for implantable MIGS devices. For more information on Pre-Submissions, please see ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf*).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on implantable MIGS devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400049 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The guidance document ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices'' refers to previously approved information collections found in FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814, subparts B and E are approved under OMB control number 0910–0231 and the collections of information in the guidance document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with

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]

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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.