4164-01-P

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; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled "Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices." This leapfrog 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.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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-2015-D-0288 for "Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://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 http://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 http://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.

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 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.

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

This guidance document recommends 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 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.

In the Federal Register of February 11, 2015 (80 FR 7614), FDA announced the availability of the draft of this guidance. Interested persons were invited to comment by May 12, 2015. FDA received and considered 12 sets of public comments and revised the guidance, where applicable. Multiple comments were received regarding the definition of glaucoma and the inclusion of pre-perimetric glaucoma. Based on discussion at the "FDA/American Glaucoma Society Workshop on Supporting Innovation for Safe and Effective Minimally Invasive Glaucoma Surgery," February 26, 2014, we do not believe that pre-perimetric glaucoma (i.e., optical coherence tomography changes and optic nerve changes without any field abnormalities) should be included in these interventional studies because there are differing opinions amongst experts about whether this condition warrants surgical treatment. This guidance is a leapfrog guidance; leapfrog 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 leapfrog guidance represents the Agency's initial thinking and our recommendations may change as more information becomes available. The current recommendations are designed to provide a conservative approach to protection of human subjects.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices." It does not establish

any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health 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.

Dated: December 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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