4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0010]

Guidance for Industry and Food and Drug Administration Staff: Investigational Device Exemption Guidance for Retinal Prostheses; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Investigational Device Exemption (IDE) Guidance for Retinal Prostheses." This guidance document describes FDA's recommendations for clinical investigations of medical devices indicated for the treatment of visual impairments resulting from retinal diseases.

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: Submit written requests for single copies of the guidance document entitled "Investigational Device Exemption (IDE) Guidance for Retinal Prostheses" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the 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:

For pre-clinical concerns:

Ethan D. Cohen,

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10903 New Hampshire Ave.,

Bldg. 62, rm. 1204,

Silver Spring, MD 20993-0002,

301-796-2485;

For clinical concerns:

Bernard P. Lepri,

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10903 New Hampshire Ave.,

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301-796-6501.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance addresses the investigation of medical devices intended to manage permanent vision impairment resulting from ocular pathology such as retinitis pigmentosa. Vision impairment, or low vision, is vision that is not correctable to normal levels by spectacles, contact lenses, medications, surgery, or other techniques and devices. It is irreversible loss of vision due to disease, not refractive errors (myopia, astigmatism, presbyopia). This guidance is intended to assist device manufacturers who plan to conduct clinical investigations of devices indicated for the treatment of vision impairment in support of premarket approval (PMA) applications, humanitarian device exemptions, or premarket notification (510(k)) submissions. The guidance describes FDA's recommendations for human clinical trials that involve the use of any type of retinal prosthesis device, including, but not limited to, visual prosthetic devices implanted on or beneath the retina, and those on or beneath the outer surface of the globe that use electrical stimulation to provide some level of visual perception for persons suffering from degenerative retinal conditions. This document does not apply to prostheses that stimulate the optic nerve or other higher brain areas such as the visual cortex or the lateral geniculate nucleus.

In the Federal Register of April 17, 2009 (74 FR 17872), FDA announced the availability of the draft guidance. Comments on the draft guidance were due by July 16, 2009. Six comments were received with each comment making multiple recommendations on changes to the content of the guidance document. The comments included recommended changes to primary, secondary, and functional vision endpoints and changes to the recommended clinical study design. In response to these comments, FDA has clarified the appropriate context for recommended endpoints and a sponsor's options with respect to use of a given endpoint. FDA also revised and clarified the recommendation regarding use of sham controls.

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 Agency's current thinking on IDE applications for retinal prostheses. 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 guidance may do so by using 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. To receive "Investigational Device Exemption (IDE) Guidance for Retinal Prostheses," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1809 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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 812 have been approved under OMB control number 0910-0078; collections of information in part 814 (21 CFR part 814), subpart H, have been approved under OMB control number 0910-0332; collections of information in 21 CFR 56.115 have been approved under OMB control number 0910-0130; and collections of information in part 814, subpart E, have been approved under OMB control number 0910-0231.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES), or electronic comments to http://www.regulations.gov. 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 28, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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