DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0010]

Draft Guidance for Industry and Food and Drug Administration Staff; Investigational Device Exemption Guidance for Retinal Prostheses; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Investigational Device Exemption (IDE) Guidance for Retinal Prostheses.'' This draft guidance document provides recommendations to industry about developing pre-clinical and clinical tests of retinal prosthetic devices for submission to FDA in an IDE application. This draft guidance is not final nor is it in effect at this time.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on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 16, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Investigational Device Exemption (IDE) Guidance for Retinal Prostheses'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.

Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Everette T. Beers, Center for Devices and Radiological Health, HFZ–460, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4200.

SUPPLEMENTARY INFORMATION:

I. Background

A retinal prosthesis is a visual prosthetic device, implanted on or beneath the retina or on the outer surface of the globe, that uses electrical stimulation to provide some level of visual stimulation for persons suffering from degenerative retinal conditions. This draft guidance helps device manufacturers submit an IDE to FDA so that they may conduct feasibility and/or pivotal human clinical trials of their retinal prostheses in the United States in order to support a premarket approval application (PMA). The draft guidance provides recommendations about pre-clinical and clinical tests of retinal prosthetic devices. The draft guidance 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.

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 investigational device exemption (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 draft guidance may do so by using the Internet. To receive ''Investigational Device Exemption (IDE) Guidance for Retinal Prostheses,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1651 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This draft 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 (the PRA) (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 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; and collections of information in 21 CFR part 814, subpart E, have been approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Dated: February 11, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–8774 Filed 4–16–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0126]

Draft Guidance for Industry on the Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for

industry entitled ''Submission of Summary Bioequivalence Data for ANDAs.'' The draft guidance is intended to assist abbreviated new drug application (ANDA) applicants in complying with the new requirements in the final rule on the submission of bioequivalence data published in the **Federal Register** in January 2009. The final rule requires ANDA applicants to submit data from all bioequivalence studies (BE studies) the applicant conducts on a drug product formulation submitted for approval, including both studies that demonstrate and studies that fail to demonstrate that a generic product meets the current bioequivalence criteria. The draft guidance provides recommendations to applicants planning to include BE studies for submission in ANDAs, and is applicable to BE studies conducted during both preapproval and postapproval periods.

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 comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 16, 2009.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Aida L. Sanchez, Center for Drug Evaluation and Research (HFD–650), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5847.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 29, 2003 (68 FR 61640), FDA published a proposed rule to require an ANDA applicant to submit data from all BE studies that the applicant conducts on a drug product formulation submitted for approval. The agency's final rule amending its bioequivalence regulations was published in the **Federal Register** on January 16, 2009 (74 FR 2849). All BE studies conducted on the same drug product formulation, including studies that demonstrate and studies that fail to demonstrate that a generic product meets the current bioequivalence criteria, must be submitted to the agency. Information from all BE studies is important to the agency for the following reasons:

- Data contained in any BE study could be important to FDA's assessment of bioequivalence for a specific product; and
- Even when additional BE studies are not critical to the agency's bioequivalence determination for the specific product being reviewed, the data provide valuable scientific information that increases the agency's knowledge and understanding of bioequivalence and generic drug development and promotes further development of science-based bioequivalence policies.

II. The Draft Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Submission of Summary Bioequivalence Data for ANDAs.'' The draft guidance provides recommendations to applicants planning to include BE studies for submission in ANDAs. The draft guidance provides information on the following subjects:

- The types of ANDA submissions covered by the new regulations on BE studies;
- A recommended format for summary reports of BE studies; and
- What formulations FDA considers the ''same drug product formulation'' for different dosage forms based on differences in composition.

The draft guidance is applicable to BE studies conducted for ANDAs during both preapproval and postapproval periods.

The 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 summary bioequivalence data reports to be submitted in ANDAs. 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 statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. Paperwork Reduction Act of 1995

The draft guidance refers to information collection provisions that 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 314.94(a)(7), 314.96(a)(1), and 314.97 have been approved under OMB control number 0910–0630.

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: April 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–8833 Filed 4–16–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Nursing Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,