

conduct relating to the development or approval, including the process for development or approval, of any drug product.

On March 5, 2012, the U.S. District Court for the District of Maryland accepted Mr. Liang's plea of guilty and adjudged him guilty of one count of making a false statement to a Federal Agency, a Federal felony offense under 18 U.S.C. 1001 and securities fraud, a Federal felony offense under 15 U.S.C. 78j(b) and 78ff.

FDA's finding that debarment is appropriate is based on the felony conviction for securities fraud referenced herein for conduct relating to the development or approval, including the process for development or approval, of any drug product. The factual basis for this conviction is as follows: Mr. Liang was a chemist for FDA, working in the Center for Drug Evaluation and Research (CDER) at the Office of New Drug Quality Assessment. As a part of his duties with FDA, Mr. Liang had access to the FDA's Document Archiving, Reporting and Regulatory Tracking Systems (DAARTS), which CDER used internally to manage, track, receive and report on new drug applications as well as emerging significant drug safety issues.

Between in or about July 2006 and in or about March 2011, Mr. Liang reviewed the DAARTS system to learn non-public information regarding when an FDA announcement regarding an experimental drug was imminent and to learn the substance of the announcement. Mr. Liang used this non-public information relating to drug approvals to cause the execution of trades on national securities exchanges, resulting in total profits and losses avoided of \$3,776,152 during that period of time.

As a result of his conviction, on November 6, 2012, FDA sent Mr. Liang a notice by certified mail proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Mr. Liang was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. The proposal also offered Mr. Liang an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal

was received on November 9, 2012. Mr. Liang failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.21), finds that Cheng Yi Liang has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product.

As a result of the foregoing finding, Mr. Liang is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see sections 306(c)(1)(B), (c)(2)(A)(ii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(ii), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Liang in any capacity during Mr. Liang's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Liang provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Liang during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Liang for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2012-N-0783 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 8, 2013.

Melinda K. Plaisier,

Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.

[FR Doc. 2013-05160 Filed 3-5-13; 8:45 am]

BILLING CODE 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, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 1204, Silver Spring, MD 20993-0002, 301-796-2485;

For clinical concerns:

Bernard P. Lepri, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2404, Silver Spring, MD 20993-0002, 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.

[FR Doc. 2013-05125 Filed 3-5-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: A Generic Submission for Formative Research, Pretesting, and Customer Satisfaction of NCI's Communication and Education Resources (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 2, 2013 (Volume 78, Page 105) and allowed 60-days for public comment. Two public comments were received and responded to. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), the National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

DATES: Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection