Dated: March 1, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–05176 Filed 3–5–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: ADP & Services Conditions for FFP for ACF.

OMB No.: 0992–0005.

Description: The Advance Planning Document (APD) process, established in the rules at 45 CFR Part 95, Subpart F, is the procedure by which States request and obtain approval for Federal financial participation in their cost of acquiring Automatic Data Processing (ADP) equipment and services. State agencies that submit APD requests provide the Department of Health and Human Services (HHS) with the following information necessary to determine the States' needs to acquire the requested ADP equipment and/or services:

(1) A statement of need;

(2) A requirements analysis and feasibility study;

(3) A procurement plan;

(4) A proposed activity schedule; and,

(5) A proposed budget.

HHS' determination of a State Agency's need to acquire requested ADP equipment or services is authorized at sections 402(a)(5), 452(a)(1), 1902(a)(4) and 1102 of the Social Security Act.

Respondents: States.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
RFP and Contract	4	1.5	4	324
Emergency Funding Request	5	.1	2	1
Biennial Reports	54	1	1.50	81
Advance Planning Document	34	1.2	120	4,896
Operational Advance Planning Document	20	1	30	600
Estimated Total Annual Burden Hours				5,902

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–05148 Filed 3–5–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0783]

Cheng Yi Liang: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Cheng Yi Liang, from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Mr. Liang was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for the development or approval, of a drug product. Mr. Liang was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Liang failed to respond. Mr. Liang's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective March 6, 2013.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual if FDA finds that the individual 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 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: