Section 810.12(a) through (b)—Based on its experience in similar situations, FDA expects that there will be only one written request for a review of cease distribution and notification order per year and that it will take approximately one staff day (8 hours) to prepare this request.

Section 810.14—Based on its experience with voluntary recalls, FDA estimates that it will take approximately two staff days (16 hours) to develop a strategy for complying with this order.

Section 810.15(a) through (d)—Based on its experience with voluntary recalls, FDA estimates that it will take approximately two staff days (16 hours) to notify each health professional, user facility, or individual of the order.

Section 810.15(e)—Based on its experience with voluntary recalls, FDA estimates that there will be approximately five consignees per recall (10 per year) who will be required to notify their consignees of the order. FDA estimates it will take them about 1 hour to do so.

Section 810.16—FDA estimates that it would take no more than one staff week (40 hours) to assemble and prepare a written status report required by a recall (§ 810.16). The status reports are prepared by manufacturers 6 to 12 times each year. Therefore, each manufacturer would spend no more than 480 hours each year preparing status reports (40 x 12). If there were two FDA invoked recalls each year, the total burden hours would be estimated at 960 hours each year (480 x 2).

Section 810.17—Based on its experience with similar procedures, FDA estimates it would take one staff day (8 hours) to draft a written request for termination of a cease distribution and notification or mandatory recall order.

Dated: November 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–28713 Filed 11–12–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1529]

Elaine Yee-Ling Lai; 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 act) debarring Ms. Elaine Yee-Ling Lai for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Lai was convicted of a felony under Federal law for aiding and abetting the making of a false document containing a materially fictitious statement in a matter within the jurisdiction of a government agency, and that Ms. Lai's conduct undermined the process for the regulation of drugs. Ms. Lai failed to request a hearing and, therefore, has waived her opportunity for a hearing concerning this action.

DATES: This order is effective November 13, 2002.

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

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On June 9, 1998, the U.S. District Court for the Central District of California accepted Ms. Lai's plea of guilty to one count of aiding and abetting the making of a false document containing a materially fictitious statement in a matter within the jurisdiction of a government agency, the FDA, in violation of 18 U.S.C. 1001(a)(3) and 2. The basis of this conviction was Ms. Lai's act in assisting the principal investigator of a clinical study in creating a fraudulent document for use by FDA to determine whether a new drug should be approved.

As a result of this conviction, FDA served Ms. Lai by certified mail on May 13, 2002, a notice proposing to debar her for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Ms. Lai an opportunity for a hearing on the proposal. The debarment proposal was based on a finding, under section 306(b)(2)(B)(i)(II) and (a)(2) of the act (21 U.S.C. 335a(b)(2)(B)(i)(II) and (a)(2)) that Ms. Lai was convicted of a felony under Federal law for aiding and abetting the making of a false document containing a materially fictitious statement in a matter within the jurisdiction of a government agency and that Ms. Lai's conduct undermined the process for the regulation of drugs. Ms. Lai was provided 30 days to file objections and to request a hearing. Ms. Lai did not request a hearing. Her failure to request a hearing constitutes a waiver of her opportunity for a hearing and a waiver of any contentions concerning her debarment.

II. Findings and Order

Therefore, the Director of the Center for Drug Evaluation and Research, under section 306(b)(2) of the act, and under authority delegated to her (21 CFR 5.99), finds that Ms. Elaine Yee-Ling Lai has been convicted of a felony under Federal law for aiding and abetting the making of a false document containing a materially fictitious statement in a matter within the jurisdiction of a government agency and that Ms. Lai's conduct undermined the process for the regulation of drugs.

As a result of the foregoing finding, Ms. Elaine Yee-Ling Lai is debarred for 5 years from providing services in any capacity to a person that has an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (see sections 306(c)(1)(B) and (c)(2)(A)(iii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Ms. Lai, in any capacity during her period of debarment, will be subject to civil money penalties. If Ms. Lai, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Ms. Lai during her period of debarment.

Any application by Ms. Lai for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 00N–1529 and sent to the Dockets Management Branch (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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 15, 2002.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 02–28715 Filed 11–12–02; 8:45 am]

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