burden is calculated for providing the guide to patients. As discussed previously, no burden can be calculated at this time for the number of AER reports that may be submitted after approval of a new drug or biologic. Therefore, the number of records that may be maintained also cannot be determined. Any burdens associated with these requirements will be reported under the AER information collection requirements. The estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

Dated: November 1, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–28854 Filed 11–12–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0355]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by December 13, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Recall Authority—21 CFR Part 810 (OMB Control Number 0910–0432)—Extension

This collection implements medical device recall authority provisions under section 518(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) and part 810 (21 CFR part 810). Section 518(e) of the act gives FDA the authority to issue an order requiring the appropriate person, including manufacturers, importers, distributors, and retailers of a device to immediately cease distribution of such device, to immediately notify health professionals and device-user facilities of the order, and to instruct such professionals and facilities to cease use of such device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death.

Section 518(e) of the act sets out a three-step procedure for issuance of a mandatory device recall order. First, if there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately: (a) Cease distribution of the device, (b) notify health professionals and device user facilities of the order, and (c) instruct those professionals and facilities to cease use of the device. Second, FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device. Third, after providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the agency determines that such an order is necessary.

The information collected under the recall authority will be used by FDA to ensure that all devices entering the market are safe and effective, to accurately and immediately detect serious problems with medical devices, and to remove dangerous and defective devices from the market.

The respondents to this proposed collection of information are manufacturers, importers, distributors, and retailers of medical devices.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
810.10(d)	2	1	2	8	16
810.11(a)	1	1	1	8	8
810.12(a) through (b)	1	1	1	8	8
810.14	2	1	2	16	32
810.15(a) through (d)	2	1	2	16	32
810.15(e)	10	1	10	1	10
810.16	2	12	24	40	960
810.17	2	1	2	8	16
Total					1,082

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Explanation of Report Burden Estimate:

The following estimates are based on FDA's experience with voluntary recalls under 21 CFR part 7. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily.

Section 810.10(d)—FDA estimates that it will take approximately 8 hours for the person named in a cease distribution and notification order to gather and submit the information required by this section. The total annual burden is 16 hours.

Section 810.11(a)—Based on its experience in similar situations, FDA expects that there will be only one request for a regulatory hearing per year and that it will take approximately one staff day (8 hours) to prepare this request.

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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