B. Annual Reporting Burden

The estimated reporting burden has been adjusted since published in the **Federal Register** at 74 FR 41133, on August 14, 2009. The adjustment is based on an evaluation of Federal Procurement Data System award information for the services applicable to FAR Clause 52.213–36, and consultation with subject matter experts within the Government that procure such services.

Respondents: 350.
Responses per Respondent: 1.
Annual Responses: 350.
Hours per Response: 24.
Total Burden Hours: 8,400
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0060, Accident Prevention Plans and Recordkeeping, in all correspondence.

Dated: September 7, 2012.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2012–22558 Filed 9–12–12; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: ORR Requirements for Refugee Cash Assistance; and Refugee Medical Assistance (45 CFR Part 400).

OMB No.: 0970–0036.

Description: As required by section 412(e) of the Immigration and Nationality Act, the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is requesting the information from Form ORR–6 to determine the effectiveness of the State cash and medical assistance, child welfare, social services, and targeted assistance programs. State-by-State Refugee Cash Assistance (RCA) and Refugee Medical Assistance (RMA) utilization rates derived from Form ORR–6 are calculated for use in formulating program initiatives, priorities, standards, budget requests, and assistance policies. ORR regulations require that State Refugee Resettlement and Wilson-Fish agencies, and local and Tribal governments complete Form ORR–6 in order to participate in the above-mentioned programs.

Respondents: State Refugee Resettlement and Wilson-Fish Agencies, local, and Tribal governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–6	50	3	3.88	582

Estimated Total Annual Burden Hours: 582.

Additional Information

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–22563 Filed 9–12–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0355]

Wayne E. Spencer: 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 Wayne E. Spencer 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 Dr. Spencer was 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 under the FD&C Act. Dr. Spencer was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation, but failed to respond. Dr. Spencer's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective September 13, 2012.

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

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., 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 a drug product under the FD&C Act.

On March 7, 2012, the U.S. District Court for the District of Kansas entered judgment against Dr. Spencer after he entered a guilty plea to, among others, a felony count of failing to prepare and maintain records required under section 505(i) of the FD&C Act, with the intent to defraud and mislead, in violation of sections 301(e) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(e), 333(a)(2), and 18 U.S.C. 2).

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein for conduct relating to the development or approval, including the process for development or approval, of a drug product under the FD&C Act.

The factual basis for this conviction is as follows: Dr. Spencer was a licensed medical doctor practicing medicine in the District of Kansas. Schering/Plough was a pharmaceutical company engaged in developing and marketing pharmaceutical products. In or about July 2009, Schering/Plough chose Lee Research Institute, Dr. Spencer's employer, to perform a clinical study known as ''A 28-Day Study Evaluating the Safety of Ragweed Sublingual Tablet in Adult Subjects 50 Years of Age and Older with Ragweed-Induced Rhino Conjunctivitis.'' Dr. Spencer was the principal investigator for the clinical study.

Before beginning the clinical study, FDA required Schering/Plough to provide the Agency with a study protocol. The study protocol contained information about how the clinical study would be conducted, where studies would be done and by whom, how the drug's safety would be evaluated, and what findings would require the study to be changed or halted. According to the study protocol, each subject had to be 50 years of age or older. Additionally, the study protocol excluded subjects who were a member or a family member of the personnel of the investigational or sponsor staff directly involved with the clinical trial. Under section 505(i) of the FD&C Act (21 U.S.C. 355(i)) and 21 CFR 312.62(b), Dr. Spencer was required to maintain adequate and accurate case histories on each individual who was administered Schering/Plough's investigational drug.

Beginning in or about January 2010, and continuing through in or about May 2010, Dr. Spencer, with the intent to defraud and mislead, failed to prepare and maintain the records required described above. Specifically, Dr. Spencer falsified the birth dates of two participants such that they appeared to be older than 50 years of age; falsely indicated that physical examinations had been performed when they had not been performed; and indicated on required forms that two participants met the inclusion criteria and had no reasons for exclusion when he knew that the participants did not meet the inclusion criteria of age and should have been excluded as employees of Lee Research Institute.

As a result of his conviction, on June 20, 2012, FDA sent Dr. Spencer 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 (21 U.S.C. 335a(a)(2)(A)), that Dr. Spencer was 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 under the FD&C Act.

The proposal also offered Dr. Spencer 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. Dr. Spencer received the proposal on June 25, 2012. He failed to respond 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, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)), under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Wayne E. Spencer 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 under the FD&C Act.

As a result of the foregoing finding, Wayne E. Spencer 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 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 section 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 Dr. Spencer, in any capacity during Dr. Spencer'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 Dr. Spencer 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 (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Spencer during his period of debarment (section 306(c)(1)(A) of the FD&C Act (21 U.S.C. 335a(c)(1)(A))).

Any application by Dr. Spencer for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA–2012–N–0355 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: September 4, 2012.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2012–22606 Filed 9–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0356]

Lisa Jean Sharp: 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 Lisa Jean Sharp 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 Lisa Jean Sharp was 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 under the