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

FD&C Act. Ms. Sharp 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. Ms. Sharp's failure to respond constitutes a waiver of her 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 26, 2012, the U.S. District Court for the District of Kansas entered judgment against Ms. Sharp after she 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: Ms. Sharp was the Director of Clinical Trials for Lee Research Institute. Schering/Plough was a pharmaceutical company engaged in developing and marketing pharmaceutical products. In or about July 2009, Schering/Plough chose Lee Research Institute, Ms. Sharp'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.'' Ms. Sharp was the Lead Clinical Research Coordinator 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), Ms. Sharp 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, Ms. Sharp, with the intent to defraud and mislead, failed to prepare and maintain the required records described above. Specifically, Ms. Sharp 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 she 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 her conviction, on June 20, 2012, FDA sent Ms. Sharp a notice by certified mail proposing to permanently debar her 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 Ms. 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 FD&C Act.

The proposal also offered Ms. Sharp an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Sharp received the proposal on June 25, 2012. She failed to respond and has, therefore, waived her opportunity for a hearing and has waived any contentions concerning her 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 Lisa Jean Sharp 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, Lisa Jean Sharp 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 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 Ms. Sharp, in any capacity during Ms. Sharp'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 Ms. Sharp provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she 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 Ms. Sharp during her period of debarment (section 306(c)(1)(A) of the FD&C Act (21 U.S.C. 335a(c)(1)(A)).

Any application by Ms. Sharp 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–0356 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. 2012–22604 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–0007]

Fee for Using a Priority Review Voucher in Fiscal Year 2013

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rates for using a tropical disease priority review voucher for fiscal year (FY) 2013. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA), authorizes FDA to determine and collect priority review user fees for certain applications for approval of drug or biological products when those applications use a priority review voucher awarded by the Secretary of Health and Human Services. These vouchers are awarded to the sponsors of certain tropical disease product applications, submitted after September 27, 2007, upon FDA approval of such applications. The amount of the fee to be submitted to FDA with applications using a priority review voucher is determined each FY based on the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous FY. This notice establishes the priority review fee rate for FY 2013.

FOR FURTHER INFORMATION CONTACT: David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–796–7103.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1102 of FDAAA (Pub. L. 110–85) added new section 524 to the FD&C Act (21 U.S.C. 360n). In section 524, Congress encouraged development of new drug and biological products for prevention and treatment of certain tropical diseases by offering additional incentives for obtaining FDA approval of such products. Under section 524, the sponsor of an eligible human drug application submitted after September 27, 2007, for a qualified tropical disease (as defined in section 524(a)(3)), shall receive a priority review voucher upon approval of the tropical disease product application. The recipient of a priority review voucher may either use the voucher with a future submission to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (21 U.S.C. 262), or transfer (including by sale) the voucher to another party that may then use it. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months.

The applicant that uses a priority review voucher is entitled to a priority review but must pay FDA a priority review user fee in addition to any other fee required by PDUFA. FDA has published a draft guidance on its Web site about how this priority review voucher program will operate (available at: *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080599.pdf*).

This notice establishes the priority review fee rate for FY 2013 as $3,559,000 and outlines FDA's process for implementing the collection of the priority review user fees. This rate is effective on October 1, 2012, and will remain in effect through September 30, 2013, for applications submitted with a priority review voucher. The payment of this priority review user fee is required in addition to the payment of any other fee that would normally apply to such an application under PDUFA before FDA will consider the application complete and acceptable for filing.

II. Priority Review User Fee for FY 2013

Under section 524(c)(2) of the FD&C Act, the amount of the priority review user fee is to be determined each FY based on the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous FY. The priority review voucher fee is intended to cover the incremental costs for FDA to do a priority review on a product that would otherwise get a standard review. The formula used in past years to calculate the priority review user fee was based on the full average cost of a priority review. After reviewing more recent data and experience with the program, FDA has revised the formula to better approximate the current and ongoing incremental FDA resource costs for a priority review. The new formula will provide the Agency with the added resources to conduct a priority review while still ensuring a robust priority review voucher program that is consistent with the Agency's public health goal of encouraging the development of new drug and biological products.

A priority review is a review conducted with a PDUFA goal date of 6 months. Normally, an application for a Center for Drug Evaluation and Research (CDER) product will qualify for a priority review if FDA determines that the product, if approved, would provide safe and effective therapy where no satisfactory alternative therapy exists or would be a significant improvement compared to marketed products, including non-drug products and/or therapies, in the treatment, diagnosis, or prevention of a disease. A Center for Biologics Evaluation and Research (CBER) product will qualify for a priority review if FDA determines that the product, if approved, would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease. FDA has committed to a goal to review and act on 90 percent of the applications that have been granted priority review status no later than 6 months after receipt. An application that does not receive a priority designation will receive a standard review. Under the goals identified in the letters referenced in section 101(b) of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), FDA commits to reviewing and acting on 90 percent of standard applications within 10 months of the date of receipt. A priority review involves a more intensive level of effort and a higher level of resources than a standard review.

Section 524 of the FD&C Act specifies that the fee amount should be based on the average cost incurred by the Agency for a priority review in the previous FY. Because FDA has never tracked the cost of reviewing applications that get priority review as a separate cost subset, FDA estimated this cost based on other data that the Agency has tracked and kept. FDA started by using data that the Agency estimates and publishes on its Web site each year—standard costs for review. FDA does not publish a standard cost for ''the review of a human drug application subject to priority review in the previous fiscal year.'' However, we expect all such applications would contain clinical data. The standard cost application categories with clinical data that FDA does publish each year are: (1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and (2) biologics license applications (BLAs).