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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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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.

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