DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Belen G. Ngo
(b) (6)

04-27-2012

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2012-N-0198

Dear Ms. Ngo:

This letter is to inform you that the Food and Drug Administration (FDA or the Agency) is proposing to issue an order debarring you for a period of five years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this proposal on a finding that you were convicted of one count of failure to establish and maintain records required under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the Act, 21 U.S.C. § 355(i)), a misdemeanor under Federal law. The conduct that served as the basis for your conviction relates to the development or approval, including the process for development or approval, of any drug product and relates to the regulation of a drug product under the Act, and the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On September 6, 2011 you entered a plea of guilty to one count of failure to establish and maintain records required under section 505(i) of the Act, in violation of 21 U.S.C. §§ 331(e) and 333(a)(1) and judgment was entered against you in the United States District Court for the Eastern District of Virginia on September 7, 2011. According to the Statement of Facts filed on September 6, 2011, the underlying facts supporting this conviction are as follows.

From on or about August 24, 2007, up to and including on or about January 30, 2008, you were employed as a clinical research coordinator by the Norfolk Diagnostic Center, doing business as, Sentara Medical Group (Sentara).

While employed by Sentara, you falsified records related to the study of Lispro insulin manufactured by Eli Lilly Corporation (Eli Lilly), a pharmaceutical company engaged in developing, testing and marketing pharmaceutical products including Lispro insulin. Eli Lilly initiated a research study to investigate the (b) (4)

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On August 24, 2007, Eli Lilly and Sentara entered into an agreement to conduct a medical research study on Lispro insulin. In accordance with the agreement, Sentara agreed to maintain adequate and accurate records in accordance with 21 C.F.R. § 312.62.

Pursuant to the study protocol, Sentara was required to maintain certain records as part of the study. The records included the case report form (CRF), which is the official record that documents a volunteer's participation in the study and contains vital medical information related to the performance of the study drug. As the clinical research coordinator, you maintained and completed the CRFs for the various study volunteers and transmitted the CRFs to Eli Lilly.

On October 2, 2007, you signed a USMD site signature and function log which described your duties as including, among other things, the following: performing measurements, collecting trial data, making CRF entries, and preparing lab samples.

On October 15, 2007, you met with patient #224 who agreed to participate in the clinical study. You recorded relevant information for patient #224's initial visit, which included clinical and laboratory assessments. After the initial visit, patient #224 stopped participating in the study and did not return for further study visits. You falsified clinical trial data asserting that patient #224 continued to participate in the study and that you collected clinical trial data on six separate visits. You also falsified entries in patient #224's daily glucose level diary.

On October 27, 2007, you met with patient #225 who agreed to participate in the clinical study. Patient #225 participated in one visit related to the study, and then stopped participating and never returned to Sentara. You falsified all records related to patient #225's second, third, fourth and fifth visits as well as all entries in patient #225's daily glucose level diary.

On October 24, 2007, patient #226 visited Sentara and agreed to participate in the clinical study. Patient #226 made three visits in connection with the clinical study and then stopped participating in the study. You falsified patient #226's records purportedly collected during an alleged fourth study visit on November 26, 2007. You also falsified all entries in patient #226's daily glucose level diary.

On October 24, 2007, patient #227 agreed to participate in the clinical study. Patient #227 participated in one visit related to the study and then stopped participating and never returned to Sentara. You falsified patient #227's records related to the second study visit.

You transmitted all of the falsified data for patient #224, #225, #226, and #227 to Eli Lilly for inclusion in its data of the clinical trial of Lispro insulin.

FDA's Finding

Section 306(b)(2)(B)(i)(I) of the Act (21 U.S.C. § 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if FDA finds that the individual has been convicted of a misdemeanor under federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under the Act, if FDA finds that the type of conduct that is the basis for the conviction undermines the process for the regulation of drugs. Your misdemeanor conviction under 21 U.S.C. §§ 331(e) and 333(a)(1) was for conduct relating to the development or approval, including the process for development or

approval of a drug product, and for conduct relating to the regulation of drug products. Because the conduct that served as the basis for your conviction occurred during a clinical trial to investigate the effectiveness of a drug product, and FDA determines whether to grant or withhold approval of a drug product based, in part, on the data from such studies, FDA finds that the actions described above relate to the development and approval, including the process for development and approval, of drug products. FDA finds that actions referred to in the Statement of Facts were also for conduct otherwise relating to the regulation of a drug product under the Act because it related to your conduct in a clinical investigation of a drug regulated by FDA. As a clinical research coordinator conducting a study for a drug product, you were required to establish and maintain certain records required under section 505(i) of the Act (21 U.S.C. § 355(i)) and section 312.62(b) of FDA's regulations (21 CFR 312.62(b)). Your conviction was directly related to your deviation from such requirements in conducting the Eli Lilly clinical investigation. Therefore, FDA finds that the type of conduct which served as the basis for your conviction undermines the process for the regulation of drugs.

The maximum period of debarment under section 306(b)(2)(B)(i)(I) (21 U.S.C. § 335a(b)(2)(B)(i)(I) is five years. Section 306(c)(3) of the Act (21 U.S.C. § 335a(c)(3)) provides six factors for consideration in determining the appropriateness and the period of a permissive debarment. The factors applicable here include: (1) the nature and seriousness of the offense involved; (2) the nature and extent of voluntary steps to mitigate the impact on the public; and (3) prior convictions involving matters within the jurisdiction of FDA.

1. Nature and seriousness of the offense.

You pled guilty to one count of failure to establish and maintain records required under section 505(i) of the Act in violation of 21 U.S.C. §§ 331(e), and 333(a)(1). On October 2, 2007, you signed the USMD site signature and function log which identified your responsibilities as a clinical research coordinator assisting in the clinical trial. You had the responsibility for collecting trial data, making CRF entries for Eli Lilly, and preparing lab samples. You admitted to repeatedly falsifying records in connection with the Eli Lilly Lispro study, including entries of glucose levels in patient diaries and clinical trial data that was to be collected during patient visits. Your admitted falsification of records extended to multiple records for multiple patients in the Lispro Study and continued until a supervisor discovered that you had falsified records related to the study at which time you were terminated.

The documentation and/or information that were falsified by you are the type that affects FDA's regulatory decisions about drug products. You repeatedly falsified records and transmitted the false data to Eli Lilly. The creation and submission of falsified clinical trial data undermines FDA's determination of safety, effectiveness, and quality of the drugs the studies were designed to assess. Accordingly, FDA concludes that the nature and seriousness of the conduct underlying your conviction as an unfavorable factor.

2. Nature and extent of voluntary steps to mitigate the impact on the public.

In determining the period of debarment, FDA shall also consider the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including, among other things, full cooperation with any investigations (including the extent of disclosure to appropriate authorities

of all wrongdoing) and any other actions taken to substantially limit potential or actual adverse effects on the public health. In your capacity as the clinical research coordinator, you were required to comply with certain recordkeeping requirements set forth in the Act and in regulations to ensure the integrity of clinical trial data and the safety of subjects. However, you repeatedly deviated from such requirements in conducting the Lispro Study. FDA has no information demonstrating that you took any voluntary steps to mitigate the impact of your actions on the public. Rather, your supervisor discovered that you had falsified data and reported the falsification to Eli Lily. Therefore, FDA considers your failure to take the actions needed to limit any potential or actual adverse effects on public health as an unfavorable factor.

3. **Prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.**

FDA is unaware of any prior convictions. The Agency will consider this as a favorable factor.

Weighing all factors, the Agency has determined that the unfavorable factors far outweigh the favorable factor, and therefore warrant the imposition of a five-year period of debarment in this case, the maximum possible period of debarment.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(b)(2)(B) of the Act (21 U.S.C. § 335a(b)(2)(B)) debarring you for a period of five years from providing services in any capacity to a person having an approved or pending drug product application. You were convicted of one count of failure to establish and maintain records required under section 505(i) of the Act, a misdemeanor under Federal law. As explained above, this offense related to the development or approval, including the process for development or approval of a drug product, and related to the regulation of drug products under the Act. Furthermore, the conduct that served as the basis for this conviction undermines the process for the regulation of drugs. Based on the factors discussed above, FDA proposes a five-year debarment period.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred as proposed in this letter.
If you decide to seek a hearing, you must file the following: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing; and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing.

The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. § 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning your debarment and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, FDA will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction permits your debarment under section 306(b)(2)(B) of the Act (21 U.S.C. § 335a(b)(2)(B)) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2012-N-0198 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. You must file four copies of all submissions pursuant to this notice of opportunity for hearing. 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.

This notice is issued under section 306 of the Act (21 U.S.C. § 335a) and under authority delegated to the Acting Director, Office of Enforcement within the Food and Drug Administration.

Sincerely,

Armando Zamora
Acting Director,
Office of Enforcement
Office of Regulatory Affairs

cc:

HF-22/Matthew Warren
HFC-130/ Michael Rogers
HFC-300/ Jeffrey Ebersole
HFC-300/Timothy Royster
GCF-1/ Seth Ray
HFD-1/Dr. John Jenkins
HFD-300/ Ilisa Bernstein
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
HFD-003/Keith Webber
HFC-2/ Michael Verdi

HFD-45/Ball, Leslie
HFD-45/Constance Lewin
HFD-45/Sherbet Samuels
HFV-200/Daniel G. McChesney

HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF