DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 9, 2015

Patricia Durr
(b) (6)

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2014-N-2100

Dear Ms. Durr:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order permanently debarring you 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, as defined in section 306(l)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. § 335a(l)(1)(B) of a felony under Federal law for conduct relating to the regulation of a drug product. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On March 28, 2014, you were convicted, as defined in section 306(l)(1)(B) of the FD&C Act, in the United States District Court for the Eastern District of Virginia, when the court accepted your plea of guilty and entered judgment against you for one count of introducing misbranded drugs into interstate commerce with the intent to defraud or mislead, in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. §§331(a) and 333(a)(2)). On April 2, 2014, judgment was entered against you in the United States District Court for the Eastern District of Virginia. The underlying facts supporting this conviction are as follows:

You were a sales representative for Gallant Pharma International Inc. (Gallant Pharma), between October 2010 and August 2013, where you were responsible for selling injectable cosmetic drugs and devices, and intravenous chemotherapy drugs, to doctors and hospitals in Massachusetts and Connecticut. At least some of the drugs that you facilitated the sale of were misbranded within the meaning of the FD&C Act.

You admitted that, on some occasions, you sold drugs which were not approved by the FDA for use on patients in the United States. You further admitted that the drugs you sold on behalf of Gallant Pharma were misbranded in that they did not bear adequate directions for use and were not subject to an exemption from that requirement, and they were accompanied by non-FDA approved packaging and inserts.

Between August 2012 and August 2013, you admitted to selling more than $699,000 in misbranded drugs and devices to doctors and medical practices in Massachusetts and Connecticut. For example, on or about August 20, 2012, you sold two-hundred forty vials of misbranded Botox to a doctor in

Southington, Connecticut, in exchange for $90,000, thereby causing misbranded drugs to be introduced into interstate commerce. You further admitted that the loss amount attributable to your personal sales, under U.S. Sentencing Guidelines, was between $400,000 and $1,000,000.

Between October 2010 and August 2013, you personally sold misbranded drugs to thirty-three distinct doctors and medical practices, and generated more than $2.6 million illegal proceeds from such sales. You admit that, as of August 2012, you became "willfully blind" to the illegality of Gallant Pharma's business. Nonetheless, you continued your sales activity with Gallant Pharma until your arrest in August 2013.

FDA's Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) 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 regulation of any drug product under the Act. As described above, you did, with the intent to mislead and defraud, introduce into interstate commerce misbranded drugs in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. §§331(a) and 333(a)(2)).

FDA finds that the conduct underlying the conduct underlying your felony conviction relates to the regulation of drug products under the FD&C Act because you undermined FDA's regulatory oversight over drug products marketed in the United States by intentionally introducing into interstate commerce drug products that did not bear adequate directions for use and were not subject to an exemption from that requirement, and which, among other things, were accompanied by non-FDA approved packaging and inserts.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. § 335a(c)(2)(A)(ii)) requires that your debarment be permanent.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) permanently debarring you from providing services in any capacity to a person having an approved or pending drug product application.

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. You should understand that the facts underlying your conviction are not at issue in this proceeding. 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.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2014-N-2100 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 Director, Office of Enforcement & Import Operations within the Food and Drug Administration.

Sincerely,

/s/

Douglas Stearn
Director
Office of Enforcement & Import Operations