DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William Ralph Kincaid
(b) (6)

5/20/2015

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2015-N-0890

Dear Dr. Kincaid:

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 June 24, 2013, 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 Tennessee, when the court accepted your plea of guilty and entered judgment against you for one count of receiving in interstate commerce a misbranded drug with intent to defraud or mislead, in violation of 21 U.S.C. § 331(c). The underlying facts supporting this conviction are as follows.

You were a medical doctor licensed to practice medicine in the State of Tennessee, and the president, majority owner, and managing partner of East Tennessee Hematology-Oncology Associates, P.C., (McLeod Cancer). McLeod Cancer was a professional corporation providing care and treatment for patients with cancer and blood diseases.

As part of the treatment of patients with cancer and other diseases, McLeod Cancer purchased large amounts of assorted prescription drugs, including chemotherapy drugs, which you prescribed and which were administered and dispensed through McLeod Cancer. McLeod Cancer sought reimbursement for the drugs and their administration from Medicare and Medicaid (TennCare) programs, as well as other health benefits programs.

Beginning in 2007, McLeod Cancer began obtaining drugs from a Canadian business, Quality Specialty Products (QSP). The drugs had been obtained from foreign sources and had not been approved by the U.S. Food and Drug Administration for distribution or use in the United States.

After nurses at McLeod Cancer raised concerns in late 2007 and early 2008 about chemotherapy drugs with foreign labeling, the clinic stopped ordering drugs from QSP. In August 2009, you and

your business manager met with a QSP representative and began ordering the misbranded unapproved drugs again. To conceal your purchase of misbranded drugs you directed the office manager to have the drugs shipped to a storage business which you owned in part. Once the drugs were received at the storage business, they were transported to the business managers' office at McLeod Cancer and they were then placed into the clinic's drug storage and control system, where the misbranded drugs were mingled with FDA-approved drugs from legitimate sources.

McLeod Cancer obtained misbranded unapproved drugs from approximately September 2007 to early 2008 and from August 2009 to February 2012, purchasing over $2 million in misbranded unapproved drugs, providing those drugs to patients, and billing Medicare, TennCare, and other government health benefits programs approximately $2.5 million for the unapproved drugs.

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, receive in interstate commerce misbranded drugs in violation of 21 U.S.C. §331(c).

Specifically, from approximately September 2007 to early 2008 and from August 2009 to February 2012, you purchased over $2 million in misbranded unapproved drugs and provided those drugs to your patients. You concealed your purchase of the misbranded drugs by having them shipped to a storage business which you owned in part. You then billed Medicare, Tenncare, and other government health benefits programs approximately $2.5 million for the unapproved drugs.

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.

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-2015-N-0890 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