DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 17, 2017

Keith J. Pierce, M.D.
Michigan Institute of Medicine
38525 Eight Mile Road
Livonia, MI 48152

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2017-N-1277

Dear Dr. Pierce:

This letter is to inform you that the Food and Drug Administration (FDA) 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, as defined in section 306(l)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. § 335a(l)(1)(B))[1] of failure to maintain records required under section 505 of the Act (21 U.S.C. 355(i)) and FDA's regulations at 21 CFR 312.62), a misdemeanor under Federal law. The conduct that served as the basis for your misdemeanor conviction relates to the development or approval, including the process for development or approval, of a drug product under the Act. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On March 3, 2016, you were convicted, as defined in section 306(l)(1)(B) of the Act, in the United States District Court Eastern District of Michigan, when the court accepted your plea of guilty and entered judgment against you for one count of failure to establish and maintain records required under section 505 of the Act (21 U.S.C. 355(i)) and FDA's regulations at 21 CFR 312.62, which is a federal misdemeanor offense under 21 U.S.C. § 331(e) & 333(a)(1).
In 2003, Aventis Pharmaceuticals operated a clinical trial for Ketek (Telithromycin), investigating its use as a drug to treat (b) (4) ((b) (4)). This clinical trial was conducted pursuant to an investigational new drug application "IND" held by Aventis Pharmaceuticals, and was therefore subject to the FDA's oversight and jurisdiction. (See Food, Drug, and Cosmetic Act at § 505(i) and FDA regulations at 21 CFR Part 312). At the time of the conduct in question, you were licensed to practice medicine under the laws of Michigan. Between approximately April and July of 2003, you served as an investigator under the IND by conducting clinical testing of Ketek on patients in your medical practice.

[1] [1] Under section 306(l)(1)(B) of the Act (21 U.S.C. § 3351(l)(1)(B)), for debarment purposes, a person is considered to have been convicted of a criminal offense when a plea of guilty has been accepted by a Federal court.

FDA's regulations at 21 CFR Part 312 require, among other things, that clinical investigators, "prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation." (21 CFR 312.62(b)). "[T]he failure to establish or maintain any record. . . required under . . . section 505(i)" of the FD&C Act is a prohibited act under the FD&C Act section 301(e) and 303(a) (21 U.S.C. 331(c) and 333(a)). Records required under section 505(i) of the FD&C Act (21 U.S.C. § 355(i)) include records required to be kept under FDA's regulations at 21 CFR 312.62. Between approximately April and July of 2003 you failed to "maintain adequate and accurate case histories . . . on each individual administered the investigational drug or employed as a control in the investigation," as required by 21 CFR 312.62. In particular, you failed to adequately and accurately document information about trial participants' previous research participation and relevant medical histories.

FDA's Finding

Section 306(b)(2)(B) of the Act (21 U.S.C. § 335a(b)(2)(B))) permits the 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 under the Act. As described above, your misdemeanor conviction under 21 U.S.C. 331(e) and 333(a)(1) was for illegal conduct relating to the development or approval of Ketek (Telithromycin) for the treatment of (b) (4) in that you failed to maintain adequate and accurate case histories for individuals in your clinical investigations. FDA finds that your conduct undermined the Agency's ability to rely on clinical data obtained in the process of developing new drugs for approval and therefore related to the development or approval of a drug product under the Act.

The maximum period of debarment under section 306(b)(2)(B), 21 U.S.C. 335a(b)(2)(B) is five years. 21 U.S.C. 335a(c)(2)(A)(iii). Section 306(c)(3) of the Act (21 U.S.C. 335a(c)(3)) provides six factors to be considered by the Agency in determining the appropriateness of and length of your debarment. The factors applicable here include: (1) nature and seriousness of the offense involved, (2) nature and extent of management participation in this offense, (3) nature and extent of voluntary steps to mitigate the impact on the public, and (4) prior convictions under the Act or involving matters within the jurisdiction of FDA.

1. **Nature and seriousness of the offense.**

You were convicted of one count to maintain records required under section 505 of the Act (21 U.S.C. 355(i)) and FDA's regulations at 21 CFR 312.62. You were a licensed physician who agreed to perform clinical testing of Ketek on patients in your medical practice, pursuant to an IND held by Aventis Pharmaceuticals. Under 21 CFR 312.62(b), a clinical investigator is required to maintain adequate and accurate case histories relating to the clinical use of investigational new drugs. You pled guilty admitting that in or about April, 2003, through in or about July, 2003, while conducting clinical testing of the drug Ketek, you failed to establish and maintain adequate and accurate records of the testing, in that you maintained inadequate and inaccurate patient case histories.

Under Title 21, United States Code, Section 355(i), FDA regulates the use of investigational new drugs. Under this section, FDA is authorized to issue regulations requiring the establishment and maintenance of records relating to the investigational or experimental use of new drugs. Your failure to maintain adequate case histories undermines the ability of the studies to adequately support a determination by the Agency regarding the safety, effectiveness, and quality of the drugs the studies were designed to assess. This, in turn, could affect FDA's ability to assess the safety and effectiveness of the drug product for use in the treatment of patients. Accordingly, FDA concludes that the nature and seriousness of the conduct underlying your conviction warrant the maximum possible period of debarment.

2. **The nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense.**

In determining the appropriate period of debarment, FDA shall also consider the nature and extent of management participation in the offense and whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense. You agreed to participate in a clinical trial at your medical practice. You were therefore in a position of authority to ensure that adequate and accurate case histories relating to the use of investigational new drugs were prepared and maintained. You failed to ensure that adequate and accurate case histories on each individual under the clinical investigation you were conducting were established and maintained. Therefore, FDA considers the nature and extent of your management participation as an unfavorable factor.

3. **Nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigation (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on public health.**

FDA has no information demonstrating that you took any voluntary steps to mitigate the impact of your actions on the public. Accordingly, the Agency considers your failure to take voluntary steps to mitigate the offense you committed to be an unfavorable factor.

4. **Prior convictions under the Act or involving matters within the jurisdiction of FDA.**

FDA is unaware of any additional criminal convictions. The Agency will consider this a favorable factor.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA has concluded that the unfavorable factors cumulatively outweigh the favorable factors and that debarment is appropriate. Accordingly, FDA proposes to issue an order under section 306(b)(2)(B)(i)(I) of the Act 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.

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-2017-N-1277 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 and Import Operations within the Food and Drug Administration.

Sincerely,

/s/
Douglas Stearn
Director
Office of Enforcement & Import Operations
Office of Regulatory Affairs