4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1277]

Keith J. Pierce: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Dr. Keith J. Pierce for a period of 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Pierce was convicted of a misdemeanor 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. Dr. Pierce was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Pierce failed to request a hearing. Dr. Pierce's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit applications for special termination of debarment to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs (ELEM 4144), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)) permits debarment of 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 FD&C Act. On March 3, 2016, the U.S. District Court for the Eastern District of Michigan entered judgment against Dr. Pierce for one count of failure to maintain records required under section 505(i) of the FD&C Act (21 U.S.C. 355(i)) and FDA's regulations at § 312.62(b) (21 CFR 312.62(b)), a Federal misdemeanor offense under the FD&C Act sections 301(e) and 303(a) (21 U.S.C. 331(e) and 333(a)(1)).

FDA's finding that the debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for this conviction was as follows: at the time the conduct underlying the conviction occurred, Dr. Pierce was licensed to practice medicine under the laws of Michigan. In 2003, Aventis Pharmaceuticals operated a clinical trial for KETEK (telithromycin), investigating its use as a drug to treat acute maxillary sinusitis (AMS). This clinical trial was conducted pursuant to an investigational new drug application (IND) held by Aventis Pharmaceuticals, and was therefore subject to FDA's oversight and jurisdiction. (see section 505(i) of the FD&C Act and part 312 (21 CFR part 312)). Between approximately April and July 2003, Dr. Pierce served as an investigator under the IND by conducting clinical testing of KETEK on patients in his medical practice. FDA's regulations at 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. The failure to establish or maintain any record required under section 505(i) of the FD&C Act is a prohibited act under sections 301(e) and 303(a) of the FD&C Act. Records required under section 505(i) of the FD&C Act include records required to be kept under FDA's regulations at § 312.62. Between approximately April and July 2003, Dr. Pierce 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 § 312.62. In particular, Dr. Pierce failed to adequately and accurately document information about trial participants' previous research participation and relevant medical histories.

As a result of his conviction, on July 17, 2017, FDA sent Dr. Pierce a notice by certified mail proposing to debar him for a period of 5 years 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(b)(2)(B) of the FD&C Act, that Dr. Pierce was 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 FD&C Act. FDA determined that Dr. Pierce's misdemeanor conviction was for illegal conduct relating to the development or approval of KETEK (telithromycin) for the treatment of AMS in that he failed to maintain adequate and accurate case histories for individuals in his clinical investigations. FDA finds that Dr. Pierce's 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 FD&C Act. The proposal also offered Dr. Pierce an

opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on July 24, 2017. Dr. Pierce failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Dr. Keith J. Pierce 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 a drug product under the FD&C Act.

As a result of the foregoing finding, Dr. Keith J. Pierce is debarred for 5 years 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 sections 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(iii) of the FD&C Act (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(iii)). 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 Dr. Pierce, in any capacity during his 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 Dr. Pierce provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the

FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications from Dr. Pierce during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Pierce for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2017-N-1277 and sent to the Dockets Management Staff (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by § 10.20.

Publicly available submissions may be seen in the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 14, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-27485 Filed: 12/20/2017 8:45 am; Publication Date: 12/21/2017]