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 December 21, 2017.

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.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Privacy Act of 1974; Matching Program

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with subsection (e)(12) of the Privacy Act of 1974, as amended, the Department of Health and Human Services, Administration for Children and Families, Office of Child Support Enforcement (HHS/ACF/OCSE), is providing notice of a re-established matching program between OCSE and state workforce agencies (SWAs) administering the Unemployment Compensation (UC) Program. The matching program will provide SWAs with new hire (*i.e.,* employment status) and quarterly wage information from OCSE's National Directory of New Hires (NDNH) system of records, for the purpose of assisting SWAs in preventing, detecting, and addressing program violations and errors, and for related secondary purposes.

DATES: The deadline for comments on this notice is January 22, 2018. The re-established matching program will commence not sooner than 30 days after publication of this notice, provided no comments are received that warrant a change to this notice. The matching program will be conducted for an initial term of 18 months (approximately January 13, 2018 through July 13, 2019) and within 3 months of expiration may be renewed for up to 12 additional months if the parties make no change to the matching program and certify that the program has been conducted in compliance with the matching agreement.

ADDRESSES: Interested parties may submit written comments on this notice, by mail or email, to Linda Boyer, Director, Division of Federal Systems, Office of Child Support Enforcement, Administration for Children and Families, by email at *linda.boyer@acf.hhs.gov,* or by mail at Mary E. Switzer Building, 330 C Street SW, 5th Floor, Washington, DC 20201. Comments received will be available for public inspection at this address from 9:00 a.m. to 5:00 p.m. ET, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: General questions about the matching program may be submitted to Linda Boyer, Director, Division of Federal Systems, Office of Child Support Enforcement, Administration for Children and Families, by email at *linda.boyer@acf.hhs.gov,* by mail at Mary E. Switzer Building, 330 C Street SW, 5th Floor, Washington, DC 20201, or by telephone at 202–401–5410.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, as amended (5 U.S.C. 552a), provides for certain protections for individuals applying for and receiving federal benefits. The law governs the use of computer matching by federal agencies when records in a system of records (meaning, records about individual retrieved by personal identifier) are matched with other federal or state agency records. The Privacy Act requires agencies involved in a matching program to:

1. Enter into a written agreement, which must be prepared in accordance with the Privacy Act, approved by the Data Integrity Board of each participating federal agency, provided to Congress and the Office of Management and Budget (OMB), and made available to the public, as required by 5 U.S.C. 552a(o), (u)(3)(A), and (u)(4).

2. Notify the individuals whose information will be used in the matching program that the information they provide is subject to verification through matching, as required by 5 U.S.C. 552a(o)(1)(D).

3. Verify match findings before suspending, terminating, reducing, or making a final denial of an individual's benefits or payments or taking other adverse action against the individual, as required by 5 U.S.C. 552a(p).

4. Report the matching program to Congress and the OMB, in advance and annually, as required by 5 U.S.C. 552a(o) (2)(A)(i), (r), and (u)(3)(D).

5. Publish advance notice of the matching program in the **Federal Register** as required by 5 U.S.C. 552a(e)(12).

This matching program meets these requirements.

Participating Agencies

Office of Child Support Enforcement (OCSE) is the source agency, and state workforce agencies (SWAs) administering the Unemployment Compensation (UC) Program are the recipient agencies.

Authority for Conducting the Matching Program

42 U.S.C. 653(j)(8).

Purpose(s)

The matching program provides each SWA with new hire and quarterly wage information from OCSE's National Directory of New Hires (NDNH) system of records, pertaining to adult UC applicants and recipients, resulting from comparing client name and Social Security number combinations in the SWA's files to data in NDNH. The match results assist the SWAs in establishing or verifying eligibility for assistance, reducing payment errors, and maintaining program integrity, including determining whether duplicate participation exists or if the client resides in another state. The SWAs may also use the NDNH information for secondary purposes, such as updating UC recipients' reported participation in work activities, updating recipients' and their employers' contact information, and administering the SWAs' tax compliance function.

Categories of Individuals

The categories of individuals whose information is involved in the matching program are adult members of households who receive or have applied for UC benefits.

Categories of Records

The categories of records involved in the matching program are new hire and quarterly wage information. The specific data elements that will be provided to OCSE in a SWA input file are:

- Submitting state code (2-digit FIPS code)
- Date stamp (input file transmission date)