be introduced in interstate commerce were misbranded because the drugs were dangerous to health when used as labeled and because the labeling on the drugs regarding use by dates and the strength of the ingredients were false and misleading. Mr. Tighe assured healthcare providers that they were receiving drug products from Med Prep that were produced in full compliance with the law, were compounded and packaged in compliance with chapter 797 of the United States Pharmacopeia (USP 797) and would be safe for patients. Mr. Tighe also told healthcare providers that the beyond use dates that Mr. Tighe assigned to sterile drug products were supported by sterility testing that satisfied the requirements of USP 797. These representations were made in, among other places, quarterly reports that were sent by email to healthcare providers and on Med Prep's website. Mr. Tighe did not inform healthcare providers of failures to comply with USP 797 and basic sterility practices, and breaches of aseptic technique in Med Prep's cleanroom, which occurred repeatedly at Med Prep's facility.

By engaging in this conduct, Mr. Tighe violated Federal and State law applicable to drug preparation and created serious risks for patients who were being treated for cancer and other illnesses. Mr. Tighe misrepresented the quality of Med Prep's drug processing and repackaging operations to increase market share, and he engaged in substandard practices to save money and increase his profits. Relying on these misrepresentations and omissions, healthcare providers paid Med Prep approximately $34,970,881 for its services between approximately 2007 and 2012.

Based on his conviction, FDA sent Mr. Tighe by certified mail on October 25, 2019, a notice proposing to permanently debar him 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(a)(2)(B) of the FD&C Act, that Mr. Tighe was convicted, as set forth in section 306(*l*)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Tighe 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 file a timely request for a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Tighe received the proposal on October 31, 2019. Mr. Tighe did not request a hearing 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 Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Gerald Tighe has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Gerald Tighe is permanently debarred 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), applicable (see **DATES**) (see sections 201(dd) and 306(c)(1)(B) and (c)(2)(A)(ii) of the FD&C Act (21 U.S.C. 321(dd) and 335a(c)(1)(B) and (c)(2)(A)(ii))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Gerald Tighe 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 Mr. Tighe 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 Mr. Tighe during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Tighe for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2019–N–3591 and sent to the Dockets Management Staff (see **ADDRESSES**). You can submit only one copy for all such submissions. The public availability of information in these submissions is governed by 21 CFR 10.20.

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

Dated: March 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05714 Filed 3–18–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4054]

Brenda Elise Edwards: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Brenda Elise Edwards 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 Mrs. Edwards was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mrs. Edwards was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of January 2, 2020 (30 days after receipt of the notice), Mrs. Edwards had not responded. Mrs. Edwards's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable March 19, 2020.

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: Jaime Espinosa, Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, *debarments@fda.hhs.gov,* 240–402–8743.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending

drug product application 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 FD&C Act. On January 28, 2019, Mrs. Edwards was convicted as defined in section 306(*l*)(1)(A) of the FD&C Act when judgment was entered against her in the U.S. District Court for the Middle District of Tennessee, Nashville Division, after her plea of guilty, to one count of conspiracy to commit mail fraud in violation of 18 U.S.C. 371.

The factual basis for this conviction is as follows: As contained in count 1 of the indictment, filed on January 17, 2013, to which Mrs. Edwards pleaded guilty, from December 2006 through August 2009, Mrs. Edwards, along with others, through Cumberland Distribution, Inc. (Cumberland), a company Mrs. Edwards was an employee of, was engaged in wholesale distribution of prescription drugs as defined by section 505(e) of the FD&C Act (21 U.S.C. 355(e)). Cumberland purchased millions of dollars of prescription drugs from unlicensed drug suppliers who were not authorized to distribute drugs under section 503 of the FD&C Act (21 U.S.C. 353). Mrs. Edwards knew that these unlicensed suppliers often procured drugs from street level drug diverters who had obtained the drugs from persons with legitimate prescriptions. On many occasions, Mrs. Edwards, along with others, had drugs shipped to shell companies, which Cumberland used as pass-throughs to create the appearance that Cumberland was purchasing drugs from licensed suppliers when in fact Cumberland was purchasing drugs from unlicensed suppliers. Afterwards, Mrs. Edwards, along with others, had these drugs shipped to Cumberland's Nashville warehouse where they were re-packaged and shipped to independent pharmacies around the country.

Mrs. Edwards also directed Cumberland employees to take steps to make it appear that the diverted drugs were purchased from authorized sellers, such as by: (1) Cleaning pharmaceutical bottles to remove evidence of glue, dirt or hair; (2) inspecting bottles for signs of diversion, such as scratches in the label, glue residue, broken seal, expired product, or illegible lot numbers; and (3) attaching patient information pamphlets to bottles that did not have them. The diverted drugs included drugs used to combat human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), antipsychotic medications, anti-depressants, blood pressure medications, and diabetes medications, among others. Through the course of this scheme, Cumberland had gross proceeds of approximately $58,984,912. Mrs. Edwards and two others obtained profits of approximately $14,689,782.

As a result of this conviction, FDA sent Mrs. Edwards by certified mail on November 18, 2019, a notice proposing to permanently debar her 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(a)(2)(B) of the FD&C Act, that Mrs. Edwards was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mrs. Edwards an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to file a timely request for a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mrs. Edwards received the proposal on December 2, 2019. Mrs. Edwards did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act), under authority delegated to the Assistant Commissioner, finds that Brenda Elise Edwards has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Brenda Elise Edwards is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, applicable (see DATES) (see section 306(a)(2)(B) and (c)(2)(A)(ii) of the FD&C Act). 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 Brenda Elise Edwards, in any capacity during her 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 Mrs. Edwards provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she 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 Mrs. Edwards during her period of debarment, other than in connection with an audit under section 306(c)(1)(B) of the FD&C Act. Note that, for purposes of section 306 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 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) (see section 201(dd) of the FD&C Act (21 U.S.C. 321(dd)).

Any application by Mrs. Edwards for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2019–N–4054 and sent to the Dockets Management Staff (see **ADDRESSES**). All such submissions are to be filed in four copies (21 CFR 10.20(a)). The public availability of information in these submissions is governed by 21 CFR 10.20.

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

Dated: March 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05717 Filed 3–18–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3608]

Stephen Kalinoski: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Stephen Kalinoski 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 Mr. Kalinoski was convicted of a felony for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Kalinoski was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Kalinoski failed to respond. Mr. Kalinoski's failure to request a hearing within the prescribed timeframe