necessary to the litigation, and that the use of such records is for a purpose that is compatible with the purpose for which the agency collected the records.

8. Congressional Inquiries—To provide information to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the written request of that individual.

9. Government-wide Program Management and Oversight—To provide information to the DOJ to obtain the department's advice regarding disclosure obligations under the Freedom of Information Act (FOIA); or to the Office of Management and Budget (OMB) to obtain that office's advice regarding obligations under the Privacy Act.

10. Breach Notification—To appropriate agencies, entities, and persons when: (a) the Commission suspects or has confirmed that there has been a breach of Personally Identifiable Information (PII) maintained in the system of records; (b) the Commission has determined that as a result of the suspected or confirmed compromise there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

11. Assistance to Federal Agencies and Entities Related to Breaches—To another Federal agency or Federal entity, when the Commission determines that information from this system is reasonably necessary to assist the recipient agency or entity in: (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, program, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

12. Non-Federal Personnel—To disclose information to non-Federal personnel, including contractors, FCC program administrators (including USAC), other vendors (*e.g.,* identity verification services), grantees, and volunteers who have been engaged to assist the FCC in the performance of a contract, service, grant, cooperative agreement, or other activity related to this system of records and who need to have access to the records to perform their activity.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

This is a cloud-based computing system that utilizes the provider-supported application on the provider's cloud network (Software as a Service or SaaS).

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records in this system of records can be retrieved by any category field, *e.g.,* first or last name or email address.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The information in this system is maintained and disposed of in accordance with the NARA General Records Schedule 6.5, Item 020 (DAA–0173–2019–0002).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The electronic records, files, and data are stored within FCC or a vendor's accreditation boundaries and maintained in a database housed in the FCC's or vendor's computer network databases. Access to the electronic files is restricted to authorized employees and contractors; and to IT staff, contractors, and vendors who maintain the IT networks and services. Other employees and contractors may be granted access on a need-to-know basis. The electronic files and records are protected by the FCC and third-party privacy safeguards, a comprehensive and dynamic set of IT safety and security protocols and features that are designed to meet all Federal privacy standards, including those required by the Federal Information Security Modernization Act of 2014 (FISMA), OMB, and the National Institute of Standards and Technology (NIST).

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to and/or amendment of records about themselves should follow the Notification Procedure below.

CONTESTING RECORD PROCEDURES:

Individuals wishing to request access to and/or amendment of records about themselves should follow the Notification Procedure below.

NOTIFICATION PROCEDURES:

Individuals wishing to determine whether this system of records contains information about themselves may do so by writing to *privacy@fcc.gov.* Individuals requesting access or amendment of records must also comply with the FCC's Privacy Act regulations regarding verification of identity as required under 47 CFR part 0, subpart E.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

88 FR 60459 (September 1, 2023).

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2024–05957 Filed 3–20–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Tuesday, March 26, 2024, at 10 a.m. and its continuation at the conclusion of the open meeting on March 27, 2024.

PLACE: 1050 First Street NE, Washington, DC and virtual (this meeting will be a hybrid meeting).

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109.

Investigatory records complied for law enforcement purposes and production would disclose investigative techniques.

Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Laura E. Sinram,

Secretary and Clerk of the Commission.

[FR Doc. 2024–06081 Filed 3–19–24; 11:15 am]

BILLING CODE 6715–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4721]

Willis Reed: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Willis Reed 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. Reed was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Reed was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of February 10, 2024 (30 days after receipt of the notice), Mr. Reed has not responded. Mr. Reed's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable March 21, 2024.

ADDRESSES: Any application by Mr. Reed for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–4721. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act 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 October 12, 2023, Mr. Reed was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of Texas-Beaumont Division, when the court entered judgment against him after his plea of guilty of conspiracy to traffick in drugs with counterfeit mark in violation of 18 U.S.C. 371 and 18 U.S.C. 2320(a)(4). The underlying facts supporting the conviction are as follows: As contained in the Second Superseding Indictment, and as contained in Factual Basis, from approximately April 2015 until January 2019, Mr. Reed conspired with drug traffickers to distribute misbranded and counterfeit cough syrup. Specifically, he worked for Woodfield Pharmaceutical LLC, as its Production Manager, and later, he was promoted to Director of Technical Operations. Woodfield Pharmaceutical LLC was part of a group of pharmaceutical companies that included Woodfield Pharmaceutical LLC, a contract manufacturing company, and Woodfield Distribution LLC, a third-party logistics company (collectively, Woodfield).

On April 25, 2014, Woodfield acquired Pernix Manufacturing LLC (Pernix). Pernix had in January 2014, entered into an agreement with Byron A. Marshall and his drug trafficking organization (DTO) to copy and manufacture cough syrup according to the directions of Marshall and his associates. Marshall was not licensed or authorized to distribute cough syrup and any background check of the personal information provided by Marshall to Pernix or later Woodfield would have revealed that he was not a licensed physician as he claimed. Initially, Marshall sought to copy Actavis Prometh VC with Codeine (Actavis). Actavis is a purple, peach-mint flavor prescription cough syrup that was in demand as a street drug. Marshall and his associates wanted to mass produce and traffic a counterfeit version of Actavis that contained promethazine, but not codeine. Cough syrups containing promethazine or codeine were approved by FDA for distribution only under the supervision of a licensed practitioner.

On April 24, 2014, Actavis Holdco U.S. discontinued production of Actavis due to its widespread abuse by recreational drug users. A Pernix product-development scientist worked with Marshall and his associates to recreate the Actavis product without codeine and promethazine to recreate the syrup base, which is a necessary component of cough syrup. Marshall and his associates would add promethazine to the counterfeit

substance prior to bottling and distribution to create the street drug. Marshall and his DTO also obtained counterfeited commercial-grade pharmaceutical labels designed to look exactly like the genuine labels for the prescription cough syrup from another supplier.

In his role with Woodfield, Mr. Reed knew that the Marshall DTO was adding active ingredients to the syrup Woodfield sold to the Marshall DTO. From approximately April 2015 until January 2019, Mr. Reed was principally responsible for the large-scale production of syrup base for the Marshall DTO. Beginning on or about May 26, 2015, Mr. Reed became the Marshall DTO's principal source of supply for promethazine. Mr. Reed brokered the promethazine from a lab chemical supplier based in New York that delivered the promethazine directly to the Marshall DTO. In January 2019 Mr. Reed was fired from his position at Woodfield.

As a result of this conviction, FDA sent Mr. Reed, by certified mail, on January 5, 2024, 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), that Mr. Reed 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 informed Mr. Reed of the proposed debarment and offered him 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. Mr. Reed received the proposal and notice of opportunity for a hearing on January 11, 2024. Mr. Reed failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived 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 Mr. Willis Reed 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, Mr. Reed is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(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 in any capacity the services of Mr. Reed 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. Reed 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 application from Mr. Reed during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B))). Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 505, 512, or 802 of this FD&C Act (21 U.S.C. 355, 360b, 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: March 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05981 Filed 3–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5470]

Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products.'' FDA is issuing this draft guidance as part of a series of guidance documents under its Real-World Evidence (RWE) Program and to satisfy, in part, a mandate under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue guidance about the use of RWE in regulatory decision-making. The draft guidance provides recommendations to sponsors who are considering submitting a non-interventional study, also referred to as an observational study, to FDA to contribute to a demonstration of substantial evidence of effectiveness and/or evidence of safety of a drug. This draft guidance was developed in response to stakeholders' growing interest in the potential use of non-interventional studies to contribute to a demonstration of the effectiveness or safety of a drug.

DATES: Submit either electronic or written comments on the draft guidance by June 18, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management