Dated: February 14, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–03234 Filed 2–16–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Food and Drug Administration/Xavier University PharmaLink Conference—Leadership in a Global Supply Chain

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in co-sponsorship with Xavier University, is announcing a public conference entitled ''FDA/Xavier University PharmaLink Conference: Leadership in a Global Supply Chain.'' The PharmaLink conference seeks solutions to important and complicated issues by aligning with the strategic priorities of FDA, and includes presentations from key FDA officials and industry experts.

DATES: The public conference will be held on March 15, 2017, from 8:30 a.m. to 5 p.m.; March 16, 2017, from 8:30 a.m. to 5 p.m.; and March 17, 2017, from 8:30 a.m. to 12:20 p.m. The conference is preceded by a Welcome Reception on March 14, 2017, from 5 p.m. to 7 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073 or 513–745–3483.

FOR FURTHER INFORMATION CONTACT:

For information regarding this notice: Nicholas Paulin, Food and Drug Administration, Cincinnati South Office, 36 East 7th St., Cincinnati, OH 45202, 513–246–4134, email: *nicholas.paulin@fda.hhs.gov.*

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207–5471, 513–745–3073, email: *phillipsm4@xavier.edu.*

SUPPLEMENTARY INFORMATION:

I. Background

The public conference helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The most pressing challenges of the global pharmaceutical industry require solutions which are inspired by collaboration to ensure the on-going health and safety of patients. These challenges include designing products with the patient in mind, building quality into the product from the starting point, selecting the right suppliers, and considering total product lifecycle systems. Meeting these challenges requires vigilance, innovation, supply chain strategy, relationship management, proactive change management, and a commitment to doing the job right the first time. FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices.

The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

The conference includes the following:

- Welcome Reception at the Hilton Netherland Plaza.
- Lunch Networking by Topic.
- The Solution ''Xchange''.
- Case Studies and Small Group Discussions.
- Action Plans.

II. Topics for Discussion at the Public Conference

The public conference will engage those involved in FDA-regulated global supply chain quality and management through the following topics:

- FDA Metrics Program—Path Forward to Reduce Risks Within FDA and Across Industry.
- Predictive Capabilities Through a Living Metrics Model.
- How Big Data and Artificial Intelligence Can Enhance Your Proactive Risk Monitoring Programs.
- Connecting Culture to Performance.
- Data Integrity—Detection and Successful Practices.
- Building a Bridge Across Generations.
- Good Supply Practices (GSPs)—Paradigm Shifting Solutions.
- How to Develop and Execute a Robust Risk-Based Due Diligence Plan.
- Maximizing Post-Merger Success.
- Your Company Bought a New Business—Now What?
- Supply Chains in China—Strategies for Regulatory Success.
- Top 3 Challenges for Successful Serialization Implementation Across Your Supply Chain.
- Strategic Direction of the Food & Drug Administration, Center for Drug Evaluation and Research (CDER), Office of Manufacturing Quality.
- Office of Regulatory Affairs Key Initiatives.
- FDA Investigator Case Study Insights.

III. Registration for the Public Conference

Registration: To register online for the public conference, please visit the ''Registration'' link on the conference Web site at *http://www.XavierPharmaLink.com.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. FDA has verified the Web site address in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Marla Phillips, 3800 Victory Pkwy., Cincinnati, OH 45207–5471. An email will be sent confirming your registration.

If you need special accommodations due to a disability, please contact Marla Phillips (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the conference.

There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 2.5 days of the conference, including the Welcome Reception that precedes the conference. There will be onsite registration if space is available. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES [1]

Attendee type	Standard rate
Industry	$1,895
Small Business (<100 employees)	1,295
Start-up Manufacturer	300
Academic	300
Media	Free

TABLE 1—REGISTRATION FEES [1]—Continued

Attendee type	Standard rate
Government	Free

[1] The fourth registration from the same company is free. Payment for the three paying registrants must be made prior to registering the fourth person free.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th St., Cincinnati, OH 45202, 513–421–9100. To make reservations online, please visit the ''Venue & Logistics'' link at *http://www.XavierPharmaLink.com.* The hotel is expected to sell out during this timeframe, so early reservation in the conference room-block is encouraged.

Dated: February 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–03176 Filed 2–16–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2191]

Raymond Sean Brown: 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) permanently debarring Dr. Raymond Sean Brown 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. Brown was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Brown was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Brown failed to request a hearing. Dr. Brown's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective February 17, 2017.

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

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

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 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 April 2, 2015, the U.S. District Court for the Eastern District of Tennessee entered judgment against Dr. Brown for one count of receiving and distributing misbranded drugs in interstate commerce with intent to defraud and mislead in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(c)), which according to section 303(a)(2) of the FD&C Act (21 U.S.C. 333(a)(2)) constitutes a felony.

FDA's finding that the debarment is appropriate based on the felony conviction referenced herein. The factual basis for this conviction is as follows: Dr. Brown was a licensed medical doctor in the state of Tennessee with a practice address listed in Cleveland, TN. The Tennessee Department of Health also lists Bradley PM&R as a licensed health care facility. Dr. Brown was the medical director of Bradley PM&R, and Dr. Brown's medical practice was listed at the same address. As a part of the treatment of patients for pain management, Bradley PM&R purchased assorted prescription drugs, including Botulinum Toxin Type A, also known as Botox Onabotulinumtoxin A (hereinafter referred to as ''Botox''), which was prescribed by Dr. Brown and was administered and dispensed through Bradley PM&R. Prior to 2009, Botox®/Botox® Cosmetic, a product manufactured by Allergan, Inc., was the only Botulinum Toxin Type A product licensed by FDA for use in humans for any indication, including pain management.

Axon Medical Supplies was a business operating in Surry, BC, Canada. Axon offered for sale to physicians and other health care providers in the United States drugs that had been obtained from foreign sources and that had not been approved by FDA for distribution or use in the United States.

From May 2008 until December 2012, Dr. Brown received $7,482,968 in reimbursement from Medicare for Botox injections alone, with none of these payments resulting from properly payable claims for FDA approved Botox injections.

Beginning in or about January 2007 and continuing through in or about December 2012, Dr. Brown ordered 254 vials (25,400 units) of Botox from Axon Medical Supplies that were misbranded within the meaning of the FD&C Act in that the drug's labeling failed to bear adequate directions for use and all words, statements, or other information required by or under authority of the FD&C Act to appear on the label and labeling were not present, in fact many of the words were not in the English language. These misbranded drugs were sent to Bradley PM&R clinic and Dr. Brown injected these drugs into his patients, while purporting them to be FDA-approved drugs.

Dr. Brown billed Medicare for all of these Botox units as if they were FDA-approved drugs. Dr. Brown also provided diluted Botox injections and billed as if they were full doses. Dr. Brown billed Medicare for an additional 15,865 vials that he did not inject into patients. Dr. Brown admitted that he received the Botox in interstate commerce for delivery that was misbranded and he acted with intent to defraud and/or mislead. Dr. Brown's conduct constituted a violation of section 303(c) of the FD&C Act, which according to section 303(a)(2) constitutes a felony.

As a result of this conviction, FDA sent Dr. Brown by certified mail on October 28, 2016, 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 Dr. Brown was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. FDA determined that Dr. Brown's felony conviction was related to the regulation of drug products because the conduct underlying his conviction undermined FDA's regulatory oversight over drug products marketed in the United States—Dr. Brown knowingly received and distributed misbranded drugs in interstate commerce with intent to defraud and mislead. The proposal also offered Dr. Brown an opportunity to