TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
M. Ophthalmic		
No new entries at this time.		
N. Orthopedic		
11–368	Standard Practice for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Tibial Components.	ASTM F3334—19.
11–369	Standard Practice for Inspection of Spinal Implants Undergoing Testing	ASTM F3292—19.
O. Physical Medicine		
No new entries at this time.		
P. Radiology		
12–331	Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems.	NEMA Standards Publication MS 14–2019.
12–332	Magnetic resonance equipment for medical imaging—Part 1: Determination of essential image quality parameters.	IEC 62464–1 Edition 2.0 2018–12.
12–333	Guidance on error and warning messages for software used in radiotherapy	IEC TR 63183 Edition 1.0 2019–12.
12–334	Radiation therapy machine characterization	AAMI RT3:2020.
Q. Software/Informatics		
13–115	Software and systems engineering—Software testing—Part 1: Concepts and definitions.	ISO/IEC/IEEE 29119–1 First edition 2013–09–01.
R. Sterility		
14–549	Standard Test Method for Evaluation of Seal Quality and Integrity Using Airborne Ultrasound.	ASTM F3004—13ε1.
S. Tissue Engineering		
No new entries at this time.		

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* Such standards are those that FDA has recognized by notice published in the **Federal Register** or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the **Federal Register**). FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to *CDRHStandardsStaff@fda.hhs.gov.* To be considered, such recommendations should contain, at a minimum, the information listed on FDA's website, which is specifically available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process.*

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04376 Filed 3–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1638]

Lawrence B. Ryan: 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 Lawrence B. Ryan 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. Ryan 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. Ryan was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred. As of October 18, 2020 (30 days after receipt of the notice), Mr. Ryan had not responded. Mr. Ryan's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable March 3, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers

Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, (ELEM–4029) Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

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 June 18, 2020, Mr. Ryan was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against him in the U.S. District Court for the Eastern District of Virginia, Norfolk Division, after his plea of guilty to one count of conspiracy to defraud the United States in violation of 18 U.S.C. 371.

The factual basis for this conviction is as follows: As contained in the Statement of Facts in Mr. Ryan's case, filed on January 8, 2020, from October 2007, and continuing through September 2010, Mr. Ryan, a physician, authorized drug orders for RX Limited (also known as RX Partners), an internet pharmacy organization that facilitated the unlawful distribution of prescription drugs to consumers throughout the United States. RX Limited had a business model whereby it allowed consumers to fill out a brief medical questionnaire, select the type of drugs the consumer desired, the desired drug strength, and the desired drug quantity and pay by credit card. RX Limited then forwarded the order to a participating physician for ''approval.'' The drugs sold by RX Limited were dispensed without a valid prescription because there was no valid doctor-patient relationship established between the authorizing physicians and the customers. Customers had no face-to-face contact with the participating physician and were not subject to any mental or physical examinations.

The physicians authorizing the orders for prescription drugs sold by RX Limited did not take patient histories or perform any diagnostic or laboratory testing, did not check the accuracy of the information customers provided (including their identities, ages, and qualifying medical conditions), and did not monitor, or provide any means to monitor, medication response. After the participating physician authorized the prescription, RX Limited sent the order to a fulfillment pharmacy, which fulfilled the order and mailed the drugs to the customer.

As a participating physician, Mr. Ryan authorized more than 158,000 drug orders for well over 10 individual RX Limited customers. Prescription drugs distributed pursuant to these orders included, FIORICET (and its generic equivalents), Carisoprodol (SOMA), Tramadol (ULTRAM), VIAGRA, CIALIS, and XENICAL. RX Limited paid Mr. Ryan $2.00 per drug order he authorized. From October 2007 through September 2010, RX Limited paid Mr. Ryan at least $316,153 for the orders he authorized.

As a result of this conviction, FDA sent Mr. Ryan by certified mail on September 11, 2020, 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. Ryan 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 Mr. Ryan 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 an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Ryan received the proposal on September 18, 2020. Mr. Ryan did not request a hearing 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 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. Ryan, 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, Mr. Ryan, 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 (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, Mr. Ryan, 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 Mr. Ryan 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. Ryan 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)). 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 Mr. Ryan for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2020–N–1638 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: February 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04375 Filed 3–2–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0008]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a