

information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” 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 to read background documents or the electronic and written/paper comments received, 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, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

FOR FURTHER INFORMATION CONTACT: Mara Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4709C, Silver Spring, MD 20993-0002, 301-796-0683.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft

guidances are posted on FDA’s website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on August 26, 2020. This notice announces draft product-specific guidances, either new or revised, that are posted on FDA’s website.

II. Drug Products For Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Ceritinib
Clobazam
Crofelemer
Diazepam
Epinephrine
Fluorodopa F-18
Lefamulin acetate
Naloxone hydrochloride; Oxycodone hydrochloride
Pretomanid
Prochlorperazine maleate
Tafamidis
Tafamidis meglumine
Vancomycin hydrochloride

III. Drug Products For Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Azelaic acid
Budesonide
Bupropion hydrochloride; Naltrexone hydrochloride
Calcipotriene
Clobetasol propionate
Desonide
Erythromycin ethylsuccinate (multiple referenced listed drugs)
Erythromycin ethylsuccinate; Sulfisoxazole acetyl

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Fluphenazine hydrochloride
Hydrocortisone acetate
Isotretinoin (multiple referenced listed drugs)
Levorphanol tartrate
Lomitapide mesylate
Methylphenidate hydrochloride
Pimavanserin tartrate
Propranolol hydrochloride (multiple referenced listed drugs)
Tofacitinib citrate

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to <https://www.regulations.gov> and enter Docket No. FDA-2007-D-0369.

These draft guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Electronic Access

Persons with access to the internet may obtain the draft guidances at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: November 13, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1394]

Richard M. Simon: 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 debaring Richard M. Simon 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 Richard M. Simon 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. Simon 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 August 6, 2020 (30 days after receipt of the notice), Mr. Simon had not responded. Mr. Simon'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 November 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, 240-402-7500.

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, debarments@fda.hhs.gov, or at 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 21, 2020, Mr. Simon 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 District of Massachusetts, after a jury verdict, on one count of Racketeering Conspiracy in violation of 18 U.S.C. 1962(d). The pattern of racketeering activity he was convicted of included engaging in multiple acts of mail fraud (18 U.S.C. 1341) and wire fraud (18 U.S.C. 1343).

The factual basis for this conviction is as follows: Mr. Simon held executive

management positions, including Regional Sales Manager for the Southeast Region and Vice President of Sales, of Insys Therapeutics Inc. (Insys), a Delaware Corporation, with headquarters in Chandler, Arizona. Insys developed and owned a drug called SUBSYS, a liquid formulation of fentanyl to be applied under the tongue. FDA approved SUBSYS for the management of breakthrough pain in adult cancer patients who are already receiving and are already tolerant to opioid therapy for their underlying persistent cancer pain. From early 2012 and continuing through 2015, Mr. Simon participated in a conspiracy whereby employees of Insys bribed medical practitioners in various states to get those practitioners to increase prescribing SUBSYS to their patients, many of whom did not have cancer. Mr. Simon, along with his co-conspirators, measured the effect of these bribes on each practitioner's prescribing habits and on the revenue that each bribed practitioner generated for Insys. Mr. Simon, along with his co-conspirators, reduced or eliminated bribes paid to those practitioners who failed to meet the minimum prescription requirements or failed to generate enough revenue to justify additional bribes.

As a result of this conviction, FDA sent Mr. Simon by certified mail on August 3, 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. Simon 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. Simon 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. Simon received the proposal on August 7, 2020. He 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. Simon 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. Simon, is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (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 Mr. Simon, 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. Simon 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. Simon during his 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 Mr. Simon for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2020-N-1394 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: November 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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