

whom they wrote the additional SUBSYS prescriptions did not have cancer. Mr. Burlakoff, along with his co-conspirators, measured the effect of the bribes and kickbacks on each practitioner's prescribing habits and on the revenue that each bribed practitioner generated. Mr. Burlakoff, along with his co-conspirators, reduced or eliminated bribes and kickbacks paid to those practitioners who failed to meet the minimum prescription requirements or failed to generate enough revenue to justify additional bribes and kickbacks.

As a result of this conviction, FDA sent Mr. Burlakoff by certified mail on July 16, 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. Burlakoff 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. Burlakoff 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. Burlakoff received the proposal on July 25, 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 Alec Burlakoff 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. Burlakoff, 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. Burlakoff, 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. Burlakoff 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. Burlakoff 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). Note that, for purposes of section 306 of the FD&C Act, a "drug product" is defined as a drug subject to regulation under 21 U.S.C. 355, 360b, or 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))).

Any application by Mr. Burlakoff for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2020-N-1372 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: December 28, 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-1412]

#### Joseph A. Rowan: 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 Joseph A. Rowan 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 Joseph A. Rowan 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. Rowan 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. Rowan had not responded. Mr. Rowan'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 January 4, 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](mailto: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 January 21, 2020, Mr. Rowan 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. Rowan held executive management positions, including Regional Sales Manager and Regional Director of the East Region 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 May 2012 and continuing until December 2015, Mr. Rowan 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. Rowan, 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. Rowan, 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.

To further this conspiracy, Mr. Rowan was involved in a scheme with his co-conspirators whereby Insys executives conspired to mislead and defraud health insurance providers to ensure those providers approved payment for SUBSYS. Insys achieved this goal by establishing the "Insys Reimbursement Center," which was designed to shift the burden of seeking prior authorization for SUBSYS from practitioners to Insys. This allowed Insys to determine what medical information was presented to insurers. Mr. Rowan and his co-conspirators directed Insys employees to mislead insurers to obtain payment authorization.

As a result of this conviction, FDA sent Mr. Rowan 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. Rowan 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. Rowan 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. Rowan 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. Rowan 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. Rowan 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 the services of Mr. Rowan, 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. Rowan 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 (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Rowan 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). 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. Rowan for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2020-N-1412 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: December 28, 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-2018-N-1129]

### Agency Information Collection Activities; Proposed Collection; Comment Request; National Agriculture and Food Defense Strategy Survey

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for a voluntary survey for the Department of Health and Human Services (HHS), the U.S. Department of Agriculture (USDA), and the Department of Homeland Security (DHS), which will inform the FDA Food Safety Modernization Act (FSMA), National Agriculture and Food Defense Strategy (NAFDS) Report to Congress. The proposed survey will be used to determine what food defense activities, if any, State, local, territorial, and/or tribal (SLTT) agencies have completed to date. The information will be compared to the initial baseline data collected by State(s) in 2018.

**DATES:** Submit either electronic or written comments on the collection of information by March 5, 2021.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 5, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 5, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

### Electronic Submissions

Submit electronic comments in the following way: