

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1347]

Michael L. Babich: 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 Michael L. Babich 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. Babich 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. Babich 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 September 2, 2020 (30 days after receipt of the notice), Mr. Babich had not responded. Mr. Babich'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 27, 2020.

ADDRESSES: Submit applications for special termination of debarment to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, 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 22, 2020, Mr. Babich 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 his plea of guilty, to one count of conspiracy in violation of 18 U.S.C. 371 and one count of wire fraud in violation of 18 U.S.C. 1341.

The factual basis for this conviction is as follows: Mr. Babich was the President and Chief Executive Officer 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. Babich conspired with other employees of Insys to bribe and provide kickbacks, often mailed through the U.S. Postal service, to medical practitioners in various states to get those practitioners to increase prescribing SUBSYS to their patients, many of whom did not have cancer. The bribes and kickbacks took various forms, including honoraria for the practitioners' participation in educational events and payment of the practitioner's staff salaries. To further this conspiracy, Mr. Babich along with his co-conspirators devised a scheme whereby Insys executives conspired to mislead and defraud health insurance providers to ensure those providers approved payment for SUBSYS when it was prescribed for non-cancer patients.

As a result of this conviction FDA sent Mr. Babich, 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. Babich 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. Babich 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. Babich received the proposal on August 3, 2020. Mr. Babich 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. Babich 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. Babich 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. Babich, 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. Babich 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. Babich 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, 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. Babich for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2020-N-1347 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 23, 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-2016-D-4437]

In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products; 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 final guidance for industry (GFI) #242 entitled “In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products.” The purpose of in-use stability testing is to establish a period of time during which a multiple-dose drug product may be used while retaining acceptable quality specifications once the container is opened (*e.g.*, after a container has been needle-punctured). This guidance reflects the Agency’s current thinking on how to formulate in-use statements, as well as how to design and carry out in-use stability studies to support these in-use statements, for multiple-dose injectable drug products intended for use in animals. This current thinking pertains to both generic drug products and pioneer drug products regardless of whether the pioneer reference listed new animal drug (RLNAD) currently has an in-use statement on the labeling.

DATES: The announcement of the guidance is published in the **Federal Register** on November 27, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2016-D-4437 for “In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products.” Received comments 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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. If you do not wish your name and contact information to be made publicly available, you can provide this 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 guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Kevin Rice, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240-402-0680, kevin.rice@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 4, 2017 (82 FR 851), FDA published the notice of availability for a draft GFI #242 entitled “In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products.” The purpose of in-use stability testing is to establish a period of time during which a multiple-dose drug product may be used while retaining acceptable quality specifications once the container is opened (*e.g.*, after a container has been needle-punctured).

FDA received two comments on the draft guidance and those comments were considered as the guidance was