appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before November 3, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 9:35 a.m. and 9:45 a.m., 10:55 a.m. and 11:05 a.m., 12 noon and 12:10 p.m., 2:05 p.m. and 2:15 p.m., 3:25 p.m. and 3:35 p.m., and 4:30 p.m. and 4:40 p.m. on November 20, 2017, and between approximately 9:40 a.m. and 9:50 a.m. and 11:10 a.m. and 11:20 a.m. on November 21, 2017. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 26, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 27, 2017.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Cindy Chee at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–23223 Filed 10–25–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0961]

Matthew Schroeder; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Matthew Schroeder's (Schroeder's) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Schroeder 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 Schroeder was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Schroeder failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable October 26, 2017.

ADDRESSES: Any application by Schroeder for special termination of debarment under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application 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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: Your application must include the Docket No. FDA–2013–N–0961. An application will be placed in the docket and, unless 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.

- *Confidential Submissions*—To submit an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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 application 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, 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 between 9 a.m.

and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, Maryland 20993, 301–796–8618.

SUPPLEMENTARY INFORMATION:

I. Background

On October 11, 2012, the U.S. District Court for the Northern District of Georgia entered a criminal judgment against Matthew Schroeder under his guilty plea. Schroeder pled guilty to a felony under the FD&C Act, namely aiding and abetting, with the intent to defraud or mislead, in the dispensing of phenazepam without a prescription, resulting in the phenazapam being misbranded while held for sale after shipment in interstate commerce in violation of sections 301(k), 503(b)(1), 303(a)(2) of the FD&C Act (21 U.S.C. 331(k), 353(b)(1) and 333(a)(2)) and 18 U.S.C. 2. Specifically, Schroeder, through his company, Novel Research Supply, and eBay ID, ''finemineralsfossilssio2'' sold phenazepam and methylenedioxypyrovalerone. Both are unapproved drugs and are used by drug users for recreational purposes. According to FDA's September 24, 2014, letter to Schroeder, in August 2010, Kevin Lewis purchased phenazepam on eBay from ''finemineralsfossilssio2'' and later died after ingesting phenazepam through an injection.

Schroeder is subject to debarment based on a finding, under section 306(a)(2) of the FD&C Act (21 U.S.C. 335a(a)(2)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. By the letter dated September 24, 2014, FDA notified Schroeder of a proposal to permanently debar him from providing services in any capacity to a person having an approved or pending drug product application. Schroeder requested a hearing on the proposal and special termination of debarment. Schroeder acknowledges his conviction under Federal law, but argues that multiple mitigating factors merit a hearing or special termination of debarment.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director of the Office of Scientific Integrity (OSI) has considered Schroeder's request for a hearing. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 21.24(b)).

The Director of OSI considered Schroeder's arguments and concludes that they are unpersuasive and fail to raise a genuine issue of fact requiring a hearing.

II. Arguments

In his request for hearing, Schroeder first argues that he took voluntary steps to mitigate the dangers posed by the drugs by putting warnings against human consumption on the sales packaging and Web site. Schroeder states that he discontinued drug sales after an FDA investigator contacted him and that he fully disclosed all of his wrongdoing. Schroeder next argues that he cooperated with investigations and provided testimony against the drug suppliers. Third, Schroeder argues that he ended all his activities concerning drug sales and has not violated the FD&C Act since September 2010. He also states that his phenazepam sales only spanned two months. Fourth, Schroeder addresses Kevin Lewis' death and purchases. Schroeder states that in the case against another drug supplier, the prosecutor determined that Kevin Lewis died from long-term IV drug use, rather than the phenazepam purchased from Schroeder's eBay account. Schroeder also clarifies that Kevin Lewis purchased the phenazepam by using his mother's eBay account. Finally, Schroeder alleges that he does not pose a recidivism risk.

Section 306(a)(2) of the FD&C Act provides FDA with the authority to debar an individual who has been convicted of certain Federal felonies. The only relevant factual issue is whether Schroeder was actually convicted of a felony under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act. Schroeder does not dispute that he pled guilty to a felony under the FD&C Act, specifically aiding and abetting, with the intent to defraud and mislead, in the dispensing of phenazepam without a prescription, resulting in the phenazepam being misbranded while held for sale after shipment in interstate commerce. Accordingly, Schroeder's arguments fail to raise a genuine and substantial issue of fact as to whether he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

Along with his request for a hearing, Schroeder also requested a special termination of debarment. Under section 306(d), a debarred individual may apply for special termination of debarment. While the debarment period can be limited to less than permanent, the individual must be debarred for at least 1 year. Schroeder is not yet debarred, so his request for special termination of debarment is not appropriate for consideration at this time.

III. Findings and Order

Therefore, the Director of OSI, under section 306(a)(2) of the FD&C Act and under the authority delegated to him, finds that Matthew Schroeder has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing findings, Matthew Schroeder is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application 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), effective (see **DATES**) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Schroeder, in any capacity during his period of debarment, will be subject to civil money penalties. See section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6)). If Schroeder, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. See 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 applications submitted by or with the assistance of Schroeder during his period of debarment.

Dated: October 20, 2017.

G. Matthew Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2017–23275 Filed 10–25–17; 8:45 am]

BILLING CODE 4164–01–P