Dated: October 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5818]

Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pharmacy Compounding Advisory Committee (PCAC). The general function of the committee is to provide advice on scientific, technical, and medical issues concerning drug compounding under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and to make appropriate recommendations to the Agency. The meeting will be open to the public.

DATES: The meeting will be held on November 20, 2017, from 8:30 a.m. to 5 p.m. and November 21, 2017, from 8:30 a.m. to 11:30 a.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–5818. The docket will close on November 17, 2017. Submit either electronic or written comments on this public meeting by November 17, 2017. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 17, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 17, 2017. 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.

Comments received on or before November 3, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

You may submit comments 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–2017–N–5818 for ''Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.

- *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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PCAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting

cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Background: Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP)); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

The Drug Quality and Security Act added a new section 503B to the FD&C Act (21 U.S.C. 353b), which created a new category of compounders termed ''outsourcing facilities.'' Under section 503B of the FD&C Act, outsourcing facilities are defined, in part, as facilities that meet certain conditions described in section 503B, including registration with FDA as an outsourcing facility. If these conditions are satisfied, a drug product compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); (2) section 505 (concerning the approval of human drug products under NDAs or ANDAs); and (3) section 582 (21 U.S.C. 360eee–1) (concerning the drug supply chain security requirements). Outsourcing facilities are not exempt from CGMP requirements in section 501(a)(2)(B) of the FD&C Act.

One of the conditions that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that a bulk drug substance (active pharmaceutical ingredient) used in a compounded drug product must meet one of the following criteria: (1) Complies with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if an applicable monograph does not exist, is a component of a drug approved by the Secretary of Health and Human Services (the Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary (the ''503A Bulks List'') (see section 503A(b)(1)(A)(i) of the FD&C Act).

Another condition that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that the compounded drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product (see section 503A(b)(3)(A) of the FD&C Act).

A condition that must be satisfied to qualify for the exemptions in section 503B of the FD&C Act is that the compounded drug is not identified (directly or as part of a category of drugs) on a list, published by the Secretary by regulation, of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients, or the drug is compounded in accordance with all applicable conditions identified on the list as conditions that are necessary to prevent the drug or category of drugs from presenting such demonstrable difficulties (see section 503B(a)(6)(A) and (B) of the FD&C Act).

FDA intends to discuss with the committee bulk drug substances nominated for inclusion on the 503A Bulks List and drug products nominated for inclusion on the list of drug products that present demonstrable difficulties for compounding under sections 503A and 503B (''Difficult to Compound List'').

Agenda: The committee intends to discuss six bulk drug substances nominated for inclusion on the section 503A Bulks List. FDA will discuss the following nominated bulk drug substances: astragalus, L-citrulline, pregnenolone, 7-keto dehydroepiandrosterone (DHEA), epigallocatechin gallate (EGCg), and resveratrol. The chart below identifies the use(s) FDA reviewed for each of the six bulk drug substances being discussed at this advisory committee meeting. The nominators of these substances will be invited to make a short presentation supporting the nomination.

Drug	Uses reviewed
Astragalus	Allergic rhinitis, asthma, diabetes, herpes simplex keratitis, wound healing.
L-citrulline	Hyperammonaemia due to cycle disorders.
Pregnenolone	Rheumatoid arthritis, hypercholesterolemia, manic and depressive symptoms of bipolar disorder and bipolar disorder with substance abuse (dual diagnosis), positive and negative symptoms of schizophrenia.
7-keto dehydroepiandrosterone	Weight loss, Raynaud's phenomena.
Epigallocatechin gallate	Treatment of obesity, wound healing, corneal neovascularization, non-alcoholic fatty liver disease, cardiac hypertrophy, diabetes (type 1 & 2), Parkinson's disease.
Resveratrol	Treatment of older adults with impaired glucose tolerance, pain.

The committee also intends to discuss liposome drug products and drug products produced using hot melt extrusion technology for inclusion on the Difficult to Compound List. Drug products produced ''by extrusion or nanotechnology'' were nominated for inclusion on the Difficult to Compound List. The nominators will be invited to make a short presentation supporting the nomination.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the

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]

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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

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- *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.