administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are listed in table 2 of this document. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations must include a current, complete resume or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also specify the advisory committee(s) for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 20, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13182 Filed 6–22–17; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA–2017–N–2697]

Submission of Proposed Recommendations for Industry on Developing Continuous Manufacturing of Solid Dosage Drug Products in Pharmaceutical Manufacturing; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: In connection with promoting the use of innovative technologies, the Food and Drug Administration (FDA or Agency) is establishing a public docket to invite discussion of issues related to the adoption of continuous manufacturing by the pharmaceutical industry.

DATES: Submit electronic or written comments by September 21, 2017.

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 September 21, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of September 21, 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.

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, 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–2697 for “Submission of Proposed Recommendations for Industry on Developing Continuous Manufacturing of Solid Dosage Drug Products in Pharmaceutical Manufacturing; Establishment of a Public Docket.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations must include a current, complete resume or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also specify the advisory committee(s) for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 20, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13182 Filed 6–22–17; 8:45 am]
BILLING CODE 4164–01–P
Submit written requests for single copies of the Engineering Research Center for Structured Organic Particulate Systems (C-SOPS) document to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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 C-SOPS document.

FOR FURTHER INFORMATION CONTACT: Sau (Larry) Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2128, Silver Spring, MD 20993–0002, 301–796–2905, Sau.Lee@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

During a May 7, 2015, workshop on the Future of Pharmaceutical Manufacturing, FDA agreed that interested parties could submit for Agency consideration draft guidance or other materials discussing the science, technology, and best practices related to continuous manufacturing. On June 13, 2016, C-SOPS submitted to FDA an industry-coordinated best practices document on continuous manufacturing. FDA is interested in public comments about the science, technology, and practices discussed in the C-SOPS document and is opening this docket for that purpose. In addition, FDA is seeking comments on other recommendations regarding continuous manufacturing that have already been published, including “Regulatory and Quality Considerations for Continuous Manufacturing: May 20–21, 2014, Continuous Manufacturing Symposium.” FDA invites comment on control strategy, facility, and process validation considerations for continuous manufacturing of solid oral dosage forms. This request is not limited to comments on the proposal described in the C-SOPS submission.

II. Electronic Access

Persons with access to the Internet may obtain the C-SOPS document at https://www.regulations.gov.


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13195 Filed 6–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3067]

Patient-Focused Drug Development for Alopecia Areata; Public Meeting: Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting and an opportunity for public comment on “Patient-Focused Drug Development for Alopecia Areata.” Patient-Focused Drug Development is part of FDA’s performance commitments under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients’ perspectives on the impact of alopecia areata, including on daily life. FDA is also seeking patients’ views on treatment approaches and decision factors taken into account when selecting a treatment.

DATES: The public meeting will be held on September 11, 2017, from 1 p.m. to 5 p.m. Submit either electronic or written comments on this public meeting by November 13, 2017. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For more information on parking and security procedures, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

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 November 13, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of November 13, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked by the delivery service acceptance receipt is on or before that date.

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–3067 for “Patient-Focused Drug Development for Alopecia Areata.” Received comments, those filed in a timely manner (see ADDRESSES), 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

SUPPLEMENTARY INFORMATION:

The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting and an opportunity for public comment on “Patient-Focused Drug Development for Alopecia Areata.” Patient-Focused Drug Development is part of FDA’s performance commitments under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients’ perspectives on the impact of alopecia areata, including on daily life. FDA is also seeking patients’ views on treatment approaches and decision factors taken into account when selecting a treatment.

DATES: The public meeting will be held on September 11, 2017, from 1 p.m. to 5 p.m. Submit either electronic or written comments on this public meeting by November 13, 2017. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For more information on parking and security procedures, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

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 November 13, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of November 13, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked by the delivery service acceptance receipt is on or before that date.

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–3067 for “Patient-Focused Drug Development for Alopecia Areata.” Received comments, those filed in a timely manner (see ADDRESSES), 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