Type of respondent	Form name	Estimated number of respondents	Number of responses per respondent	Average time per response (in hours)	Total burden hours (annual)
Project staff	Semi-annual Performance Report	18	Twice a year	8	288
Local agency leaders	Program Information Cover Sheet/Participant Information Form/Attendance Log/Post Program Survey.	700 leaders	Twice a year (one set per program).	.50	700
Local data entry staff		46 data entry staff	Once per program x 1400 programs.	.50	700
Local organization staff and local database entry staff.	Host Organization Data Form	700 staff	1	.05	35
Program participants	Participant Information Form	16,390	1	.10	1,639
Program participants	Post Program Survey	983	1	.10	983
Total Burden Hours					4,345

Dated: September 20, 2017.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2017–21179 Filed 10–2–17; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5437]

Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access.'' The purpose of the public workshop is to provide an overview of current regulatory science initiatives related to generic topical dermatological drug products, solicit public input on scientific barriers that may limit patient access to such drug products, and discuss approaches to overcome/address any such barriers. FDA is seeking public input from a variety of stakeholders, including industry, academia, patient advocates, and professional associations.

DATES: The public workshop will be held on October 20, 2017, from 8:30 a.m. to 4:30 p.m., Eastern Standard Time. Submit either electronic or written comments on this public workshop by November 20, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://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 20, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 20, 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, 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–5437 for ''Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access.'' 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 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: Sam Raney, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4706, Silver Spring, MD 20993, 240–402–7967, email: *Sameersingh.Raney@fda.hhs.gov;* or Markham Luke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4712, Silver Spring, MD 20993, 301–796–5556, email: *Markham.Luke@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The conventional approach to establish bioequivalence (BE) for most topical dermatological generic drug products relies upon clinical endpoint BE studies. The risk of failing to demonstrate BE due to the relative insensitivity of these clinical endpoint studies, combined with their burden and length, may represent a barrier to generic drug development and may adversely impact patient access to some topical dermatological generic drug products. FDA is evaluating alternative BE approaches for topical dermatological generic drug products, using methods that are more efficient, and also more sensitive and reproducible. FDA believes that these BE approaches would benefit from public discussion.

II. Topics for Discussion at the Public Workshop

This public workshop will focus on a discussion of current regulatory science initiatives intended to foster the development of topical dermatological generic drug products, examining alternative BE approaches that may be more efficient and less risky than traditional approaches. FDA is also interested in receiving public input about any barriers that may limit the use of such alternative BE approaches in the development of topical dermatological generic drug products. Public input is also sought about strategies to overcome these barriers.

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register online at *https://survey.co1.qualtrics.com/jfe/form/SV_9YQDLZJRjXtYiXz.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by October 13, 2017, midnight, Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact Sam Raney (see **FOR FURTHER INFORMATION CONTACT**) no later than October 13, 2017.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation, or to submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 16, 2017. All requests to make oral presentations must be received by the close of registration on October 9, 2017. If selected for presentation, any presentation materials must be emailed to *GDUFARegulatoryScience@fda.hhs.gov* no later than October 13, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming webcast of the public workshop: This public workshop will also be webcast. A live webcast of this workshop will be viewable at *https://collaboration.fda.gov/ogddermaldrug/* on the day of the workshop.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/Drugs/NewsEvents/ucm557252.htm.*

Dated: September 28, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21186 Filed 10–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5670]

Abbreviated New Drug Applications Submissions—Amendments To Abbreviated New Drug Applications Under the Generic Drug User Fee Act; Draft 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 draft guidance for industry entitled ''ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.'' This draft guidance is intended to explain to applicants how