Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 021015 ...	ANDROGEL	Testosterone	12.5 mg/1.25 g Actuation.	Gel, Metered; Transdermal.	AbbVie Inc.
NDA 021204 ...	STARLIX	Nateglinide	60 mg; 120 mg	Tablets; Oral	Novartis Pharms., Corp.
NDA 021217 ...	EXALGO	Hydromorphone Hydrochloride.	8 mg; 12 mg; 16 mg; 32 mg.	Tablet, Extended-Release; Oral.	Specgx, LLC.
NDA 021365 ...	LEXAPRO	Escitalopram Oxalate ..	Equal to (EQ) 5 mg Base/5 mL.	Solution; Oral	Allergan Sales, LLC.
NDA 021490 ...	FEMCON FE	Ethinyl Estradiol; Norethindrone.	0.035 mg; 0.4 mg	Tablet, Chewable; Oral	Allergan Pharms., International, Ltd.
NDA 021860 ...	SARAFEM	Fluoxetine Hydrochloride.	EQ 15 mg Base	Tablet; Oral	Allergan Pharms. International, Ltd.
NDA 021870 ...	Fludeoxyglucose F–18	Fludeoxyglucose F–18	20–200 Millicurie/mL ...	Injectable; Intravenous	Feinstein Institute Medical Research.
NDA 022442 ...	REZIRA	Hydrocodone Bitartrate; Pseudoephedrine Hydrochloride.	5 mg/5 mL; 60 mg/5 mL.	Solution; Oral	Persion Pharms., LLC.
NDA 050757 ...	PREVPAC	Amoxicillin; Clarithromycin; Lansoprazole.	500 mg; 500 mg; 30 mg.	Capsule, Tablet, Capsule; Oral.	Takeda Pharms. USA, Inc.
NDA 203195 ...	SUPRAX	Cefixime	400 mg	Capsule; Oral	Lupin, Ltd.
NDA 207931 ...	TECHNIVIE	Ombitasvir; Paritaprevir; Ritonavir.	12.5 mg; 75 mg; 50 mg	Tablet; Oral	AbbVie Inc.
NDA 208624 ...	VIEKIRA XR	Dasabuvir Sodium; Ombitasvir; Paritaprevir; Ritonavir.	EQ 200 mg Base; 8.33 mg; 50 mg; 33.33 mg.	Tablet, Extended Release; Oral.	AbbVie Inc.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06059 Filed 3–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6644]

Fiscal Year 2021 Generic Drug Science and Research Initiatives Workshop; 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 ''FY 2021 Generic Drug Science and Research Initiatives Workshop.'' The purpose of the public workshop is to provide an overview of the status of science and research initiatives for generic drugs and an opportunity for public input on these initiatives. FDA is seeking this input from a variety of stakeholders—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2017 (GDUFA II) to develop an annual list of science and research initiatives specific to generic drugs. FDA will take the information it obtains from the public workshop into account in developing its Fiscal Year (FY) 2022 GDUFA science and research initiatives.

DATES: The public workshop will be held on June 23, 2021, from 8:30 a.m. to 4:30 p.m. Eastern Time. Submit either electronic or written comments on this public workshop by July 23, 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held virtually.

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 July 23, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 23, 2021. 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–6644 for ''FY 2021 Generic Drug Science and Research Initiatives Workshop; Public Workshop; Request for Comments.'' 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, 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.

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, *Sameersingh.Raney@fda.hhs.gov;* or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4722, Silver Spring, MD 20993, 240–402–7957, *Robert.Lionberger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, Congress passed the Generic Drug User Fee Amendments of 2012 (GDUFA I) (Pub. L. 112–144). GDUFA I was designed to enhance public access to safe, high-quality generic drugs and to modernize the generic drug program. To support this goal, FDA agreed in the GDUFA I commitment letter to work with industry and interested stakeholders on identifying science and research initiatives specific to generic drugs for each fiscal year covered by GDUFA I.

In August 2017, GDUFA I was reauthorized until September 2022 through the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Pub. L. 115–52). In the GDUFA II commitment letter,[1] FDA agreed to conduct annual public workshops ''to solicit input from industry and stakeholders for inclusion in an annual list of GDUFA II [r]egulatory [s]cience initiatives.'' The public workshop scheduled for June 23, 2021, seeks to fulfill this agreement.

II. Topics for Discussion at the Public Workshop

The purpose of the public workshop is to obtain input from industry and other interested stakeholders on the identification of generic drug science and research initiatives for FY 2022.

FDA is particularly interested in receiving input in the following five topic areas:

1. What research is needed to determine how formulation differences in generic injectable products (that are not qualitatively (Q1) and quantitatively (Q2) the same as their reference listed drug products) affect the substitutability of these products?

2. What research is needed to prepare for generic versions of oligonucleotide drug products (*e.g.,* siRNA, chemically modified, antisense oligonucleotides)?

3. What research relating to artificial intelligence (including machine learning) and/or the use of integrated data from multiple areas may facilitate and modernize the development of generic products?

4. What research is needed to bridge the gap between existing scientific insights from GDUFA-funded research (*e.g.,* related to product characterization techniques or modeling and simulation tools) and the development of suitable test procedures, study designs, model integrated evidence, and/or approaches for developing generic products?

5. What research is needed to support identification of best bioequivalence practices and convergence of global bioequivalence standards?

Specific presentations and discussions at this workshop will be announced at a later date and may differ from the topics above, however, input in the above topic areas will help the Agency identify and expand our scientific focus for the next fiscal year.

FDA will consider all comments made at this workshop or received through the docket (see **ADDRESSES**) as it develops its FY 2022 science and research initiatives. Information concerning the science and research initiatives for generic drugs can be found at *https://www.fda.gov/gdufaregscience.*

III. Participating in the Public Workshop

Registration: Registration is free. Persons interested in attending this public workshop must register online at *https://www.fda.gov/drugs/news-events-human-drugs/fy-2021-generic-drug-science-and-research-initiatives-public-*

[1] The GDUFA II commitment letter is available at *https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf.*

workshop-06232021-06232021. Registration may be performed at any time before or during the workshop.

Requests for Oral Presentations: During online registration you may indicate if you wish to present your public comments. Public comment presentation requests must be submitted by 11:59 p.m. Eastern Time at the end of April 30, 2021. 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 request time for a joint presentation, or submit requests for designated representatives to participate in the workshop. Following the close of registration on April 30, 2021, at 11:59 p.m. Eastern Time, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin; we will select and notify participants by May 21, 2021. All requests to make oral presentations must be received by the close of registration on April 30, 2021. If selected for presentation, any presentation materials must be emailed to *GDUFARegulatoryScience@fda.hhs.gov* no later than June 18, 2021, 11:59 p.m. Eastern Time. 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 be webcast. Please register online (as described above) to attend the workshop remotely. Unless scheduled to participate in advance, attendees will not be able to speak or make presentations during the public comment period or during any other session of the workshop. To join the workshop via the webcast, please go to *https://www.fda.gov/drugs/news-events-human-drugs/fy-2021-generic-drug-science-and-research-initiatives-public-workshop-06232021-06232021.*

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 website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: As soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov* or at *https://www.fda.gov/gdufaregscience.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). Closed caption scrolling text will be generated by the Adobe Connect system and displayed in real time. The closed caption scrolling text will also display when streaming the recorded presentations for viewing at a later date.

Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06096 Filed 3–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1862]

The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Public Meeting; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice entitled ''The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Public Meeting; Request for Comments'' that appeared in the **Federal Register** of October 28, 2020. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice published on October 28, 2020 (85 FR 68342). Submit either electronic or written comments by June 22, 2021 to ensure that the Agency considers your comment.

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 June 22, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 22, 2021. 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–2020–N–1862 for ''The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Public Meeting; Reopening of Comment Period.'' 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, 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