Agency's website 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:

Agenda: On March 6, 2019, under Topic I, the Center for Biologics Evaluation and Research's (CBER) VRBPAC will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2019 to 2020 influenza season. Also on March 6, 2019, under Topic II, the committee will meet in open session to hear an overview of the research programs in the Laboratory of Immunoregulation (LIR) and the Laboratory of Retroviruses (LR), Division of Viral Products, Office of Vaccines Research and Review, CBER, FDA.

On March 7, 2019, under Topic III, the committee will meet in open session to discuss and make recommendations on the safety and effectiveness of Dengue Tetravalent Vaccine (Live, Attenuated) (DENGVAXIA) manufactured by Sanofi Pasteur.

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 website 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 website 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: On March 6, 2019, from 8 a.m. to 3:15 p.m., and on March 7, 2019, from 8:30 a.m. to 4:45 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 27, 2019. On March 6, 2019, oral presentations from the public will be scheduled between approximately 11:10 a.m. to 11:55 a.m. for the influenza strain selection portion of the meeting and 3 p.m. to 3:15 p.m. for the overview portion of the LIR/LR Site Visit. On March 7, 2019, oral presentations from the public will be scheduled between approximately 1:15 p.m. to 2:15 p.m. for the Dengue Tetravalent Vaccine (Live, Attenuated) (DENGVAXIA) manufactured by Sanofi Pasteur portion of the meeting. 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 February 19, 2019. 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 February 20, 2019.

Closed Committee Deliberations: On March 6, 2019, from 3:15 p.m. to 4:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making personnel and staffing decisions regarding individual scientists.

We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

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 Serina Hunter-Thomas (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website 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: January 15, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–00769 Filed 2–4–19; 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 2019 Generic Drug Regulatory Science Initiatives; 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 2019 Generic Drug Regulatory Science Initiatives.'' The purpose of the public workshop is to provide an overview of the status of regulatory science 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 regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public workshop into account in developing its fiscal year (FY) 2020 regulatory science initiatives.

DATES: The public workshop will be held on May 1, 2019, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this public workshop by June 1, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, sections B and C), 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 June 1, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 1, 2019. 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 2019 Generic Drug Regulatory Science Initiatives; 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.

- 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: Stephanie Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 3742, Silver Spring, MD 20993, 240–402–7960, *Stephanie.Choi@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 regulatory science initiatives specific to generic drugs for each fiscal year covered by GDUFA I.

In August 2017, GDUFA I was reauthorized until September 2022 through 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 May 1, 2019, 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 regulatory science initiatives for FY 2020.

FDA is particularly interested in receiving input on the following three topics:

1. FY 2019 regulatory science initiatives,[2] including specific products or actions that FDA should consider as it implements those initiatives, including, for example:

a. The value to the generic drug product industry in expanding the Biopharmaceutics Classification System Class III waivers to include non-Q1/Q2 formulations,

b. Scientific gaps that impact the prediction of the results of fed bioequivalence studies (when the drug product is administered shortly after a meal, as opposed to administration under fasting conditions), and

c. Challenges for industry in implementing new analytical or computational methods that arise from regulatory science initiatives.

2. Recently approved new drug applications that may pose scientific challenges to the future development of generic drug products referencing those applications.

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

[2] The FY 2019 regulatory science initiatives are available at *https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM626329.pdf.*

3. Regulatory science initiatives that FDA should begin to consider in FY 2019, including, for example:

a. Scientific challenges in the evaluation of sensitization for transdermal systems and

b. The development of alternative approaches to in vivo bioequivalence studies to evaluate product equivalence.

FDA will consider all comments made at this workshop or received through the docket (see **ADDRESSES**) as it develops its FY 2020 regulatory science initiatives. Information concerning the regulatory science initiatives for generic drugs can be found at *https://www.fda.gov/gdufaregscience.*

III. Participating in the Public Workshop

Registration: To register for the public workshop, please email complete contact information for each attendee—including the attendee's name, title, affiliation, address, email, and telephone number—to *GDUFARegulatoryScience@fda.hhs.gov.* Please also indicate in the email whether attendance will be by webcast or in person.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by April 1, 2019, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Stephanie Choi (see **FOR FURTHER INFORMATION CONTACT**) no later than April 1, 2019.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments (and requests to participate in the focused sessions). 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 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 April 8, 2019. All requests to make oral presentations must be received by the close of registration on April 1, 2019, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to *GDUFARegulatoryScience@fda.hhs.gov* no later than April 22, 2019, 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 also be webcast. Please register online by April 1, 2019, 11:59 p.m. Eastern Time to attend the workshop remotely. Please note that remote 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://collaboration.fda.gov/gdufa2019/.*

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: Please be advised that 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**). A link to the transcript will also be available on the internet at *https://www.fda.gov/gdufaregscience.*

Dated: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–01067 Filed 2–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0113]

Facta Farmaceutici S.p.A., et al.; Withdrawal of Approval of 23 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 7, 2019.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 062117	Cephalexin for Oral Suspension USP, Equivalent to (EQ) 100 milligrams (mg) base/milliliter (mL), EQ 125 mg base/5 mL, and EQ 250 mg base/5 mL.	Facta Farmaceutici S.p.A., c/o Interchem Corp., 120 Route, 17 North, Paramus, NJ 07652.
ANDA 062508	Erymax (erythromycin) Topical Solution USP, 2%	Merz North America, 6501 Six Forks Rd., Raleigh, NC 27615.
ANDA 075369	Enalapril Maleate Tablets USP, 10 mg and 20 mg	Krka, tovarna zdravil, d.d., Novo mesto, Slovenia, c/o KRKA USA, LLC, 4216 Cravens Point Rd., Wilmington, NC 28409.
ANDA 075370	Enalapril Maleate Tablets USP, 2.5 mg and 5 mg	Do.