

of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 6, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-19740 Filed 8-11-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0882]

#### Generic Drug User Fees; Stakeholder Meetings on Generic Drug User Fee Amendments of 2012 Reauthorization; Request for Notification of Stakeholder Intent To Participate; Extension of Closing Date

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for notification of intent to participate; extension of closing date.

**SUMMARY:** The Food and Drug Administration (FDA) is extending the closing date for the document that appeared in the **Federal Register** of June 3, 2015. In that document, FDA requested that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA). The statutory authority for GDUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to continue collecting user fees for the generic drug program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program. The FD&C Act also requires that FDA hold continued discussions with patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated industry. The purpose of the request for notification is to ensure continuity and progress in these monthly discussions

by establishing consistent stakeholder representation.

**DATES:** FDA is extending the closing date in the notice published June 3, 2015 (80 FR 31602). Submit notification of intent to participate by April 30, 2016.

**ADDRESSES:** Submit notification of intent to participate in monthly stakeholder meetings by email to [GenericDrugPolicy@fda.hhs.gov](mailto:GenericDrugPolicy@fda.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Connie Wisner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1718, Silver Spring, MD 20993-0002, 240-402-7946, [Connie.Wisner@fda.hhs.gov](mailto:Connie.Wisner@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

FDA is requesting that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify the Agency of their intent to participate in periodic consultation meetings on the reauthorization of GDUFA. GDUFA authorizes FDA to collect fees from drug companies that submit marketing applications for certain generic human drug applications, certain drug master files, and certain facilities. GDUFA requires that generic drug manufacturers pay user fees to finance critical and measurable generic drug program enhancements. The statutory authority for GDUFA expires at the end of September 2017. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human generic drug review process. Section 744C(d) (21 U.S.C. 379j-43(d)) of the FD&C Act requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program, including representatives from patient and consumer groups, health care professionals, and scientific and academic experts. FDA initiated this process on June 15, 2015, by holding a public meeting at which stakeholders and other members of the public were given an opportunity to present their views on reauthorization (April 21, 2015, 80 FR 22204). The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer groups, health care

professional associations, as well as scientific and academic experts notify FDA of their intent to participate in periodic consultation meetings on GDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensuring progress in these discussions. If you wish to participate in this part of the reauthorization process, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions as needed. Stakeholders who identify themselves through this notice will be included in all stakeholder discussions while FDA negotiates with the regulated industry. Stakeholders who decide to participate in these monthly meetings at a later time may still participate in remaining monthly meetings by notifying FDA (see **ADDRESSES**). These stakeholder discussions will satisfy the requirement in section 744C(d)(3) of the FD&C Act.

##### II. Notification of Intent To Participate in Periodic Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding GDUFA reauthorization, please provide notification by email to [GenericDrugPolicy@fda.hhs.gov](mailto:GenericDrugPolicy@fda.hhs.gov) by April 30, 2016. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting once FDA receives their notification.

Dated: August 6, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0001]

#### Pediatric Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration

(FDA). The meeting will be open to the public.

*Name of Committee:* Pediatric Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on Wednesday, September 16, 2015, from 8:30 a.m. to 5:30 p.m.

*Location:* Double Tree by Hilton, 8727 Colesville Rd., Silver Spring, MD 20910, 301-589-5200. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-hotel-washington-dc-silver-spring-DCASSDT/index.html>.

*Contact Person:* Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 301-796-0885, email: [walter.ellenberg@fda.hhs.gov](mailto:walter.ellenberg@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 <http://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.

*Agenda:* On September 16, 2015, the Pediatric Advisory Committee (PAC) will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the Pediatric Research Equity Act (Pub. L. 108-155). The PAC will meet to discuss the following products:

1. DUREZOL (difluprednate ophthalmic emulsion) 0.05%, Phenylephrine Hydrochloride Ophthalmic Solution,
2. ZYLET (loteprednol etabonate and tobramycin ophthalmic suspension),
3. BETHKIS (tobramycin Inhalation Solution),
4. INTELENCE (etravirine),
5. PREZISTA (darunavir),
6. VIRAMUNE XR (nevirapine),
7. EPIDUO (adapalene and benzoyl peroxide),
8. EXJADE (deferasirox),
9. DOTAREM (gadoterate meglumine),
10. FYCOMPA (perampanel),

11. RECOTHROM (thrombin, topical [recombinant]),

12. PREVNAR 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM<sub>197</sub> Protein]),

13. PLEXIMMUNE,

14. ELANA SURGICAL KIT (HUD),

15. BERLIN HEART EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE (VAD),

16. ENTERRA THERAPY SYSTEM, and

17. CONTEGRA Pulmonary Valved Conduit.

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 <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* 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 September 8, 2015. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. 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 September 1, 2015. 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 September 8, 2015.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg 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 <http://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: August 5, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Hypertension and Microcirculation.

*Date:* September 15, 2015.

*Time:* 10:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Katherine M. Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301-435-0912, [Katherine\\_Malinda@csr.nih.gov](mailto:Katherine_Malinda@csr.nih.gov).

*Name of Committee:* Digestive, Kidney and Urological Systems Integrated Review Group; Clinical, Integrative and Molecular Gastroenterology Study Section.

*Date:* September 28, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.