

Dated: October 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-26055 Filed 10-13-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0128]

Prescription Drug User Fee Act; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until April 29, 2016, the comment period for the notice of public meeting that appeared in the **Federal Register** of May 13, 2015 (80 FR 27323). In the notice of public meeting, FDA invited public comment as the Agency begins the process to reauthorize the Prescription Drug User Fee Act (PDUFA) in fiscal years (FYs) 2018 to 2022. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the notice of public meeting published May 13, 2015 (80 FR 27323). Submit either electronic or written comments by April 29, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2010-N-0128 for "Prescription Drug User Fee Act; Reopening of Comment Period." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/>

[regulatoryinformation/dockets/default.htm](http://www.regulations.gov).

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993-0002, 301-796-5003.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 13, 2015, FDA published a notice of public meeting with a 30-day comment period following the public meeting and invited comments as the Agency began the process to reauthorize PDUFA in FYs 2018 to 2022.

FDA is reopening the comment period until April 29, 2016. The Agency believes that reopening the comment period for the notice of public meeting will allow adequate time for interested persons to submit comments.

Dated: October 7, 2015.

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[FR Doc. 2015-26052 Filed 10-13-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-3399]

Recommendations for Microbial Vectors Used for Gene Therapy; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled "Recommendations for Microbial Vectors Used for Gene Therapy; Draft Guidance for Industry." The draft guidance provides investigational new drug application (IND) sponsors, with recommendations concerning IND submissions for microbial vectors used for gene therapy (MVGTS) in early-phase clinical trials. MVGTs meet the regulatory definition of