The Food and Drug Administration (FDA) is reopening until October 31, 2011, the comment period for the notice of public meeting that published in the Federal Register of March 16, 2010 (75 FR 12555). In the notice, FDA announced a public meeting to solicit input on the reauthorization of the Prescription Drug User Fee Act (PDUFA) program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires public review of the recommendations for the human drug review program after negotiations with the regulated industry conclude. FDA expects that this additional public process will be complete by October 2011. FDA is reopening the comment period for the expected duration of the public part of the reauthorization process to ensure that all interested stakeholders have the opportunity to share their views on the matter.

DATES: Submit either electronic or written comments by October 31, 2011.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Patrick Frey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1174, Silver Spring, MD 20993–0002, 301–796–3844, FAX: 301–847–8443, e-mail: PDUFAReauthorization@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of March 16, 2010 (75 FR 12555), FDA published a notice of a public meeting on PDUFA reauthorization and invited comments. In the notice, the Agency stated that the authority for PDUFA expires in September 2012. Without new legislation, FDA will no longer be able to collect user fees to fund the human drug review process. Section 736B(d)(2) (21 U.S.C. 379h-2(d)(2)) of the FD&C Act requires that before FDA begins negotiations with the regulated industry on PDUFA reauthorization, we do the following: (1) Publish a notice in the Federal Register requesting public input on the reauthorization, (2) hold a public meeting at which the public may present its views on the reauthorization, (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes, and (4) publish the comments on the FDA Web site.

The public meeting was held on April 12, 2010, and interested persons were given until May 12, 2010, to submit comments. The written comments submitted during that period are now published on the FDA Web site at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm215804.htm. To ensure that all interested persons have sufficient opportunity to share their views on PDUFA throughout the reauthorization process, FDA is reopening the comment period until October 31, 2011. The FD&C Act requires public review of the recommendations for the human drug review program after negotiations with the regulated industry conclude. FDA expects that the public component of the reauthorization process will be complete by October 2011. Therefore, the Agency is reopening the comment period for this anticipated duration to ensure that all interested stakeholders have the opportunity to share their views on the matter.