DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[DOCKET NO. FDA–2010–N–0381]

Generic Drug User Fee; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting to discuss proposed recommendations for enactment of a Generic Drug User Fee Act (GDUFA), which will authorize FDA to collect fees and use them for the process for the review of human generic drug applications and associated Type II Active Pharmaceutical Ingredient Drug Master Files (DMFs) and for conducting associated inspections for fiscal years (FYs) 2013–2017. New legislation would be required for FDA to establish and collect user fees under such a program.

FDA and the regulated industry have developed a proposal for Congressional consideration. In the interest of transparency, and in an effort to voluntarily follow a process similar to the ones set forth in the Federal Food, Drug, and Cosmetic Act for FDA’s other user fee programs, FDA is publishing the negotiated recommendations (the goals letter), holding a meeting at which the public may present its views on such recommendations, and providing an opportunity for the public to provide written comments on such recommendations.

Date and Time: The public meeting will be held on December 19, 2011, from 10 a.m. to 5 p.m. Registration to attend the meeting must be received by December 12, 2011. The meeting will also be Web cast. See Section III. B. of this document for information on how to register for the meeting and Section III. C. on information about how to access the Web cast. Please submit any comments that you plan to present at the public meeting to the docket by the date of the public meeting but note that written or electronic comments must be submitted by January 6, 2011.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, rm. 2047, Silver Spring, MD 20993. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the