

## Generic Drug User Fee

Under the program, which now requires Congressional approval, FDA will receive nearly \$1.5 billion over five years in supplemental funding through industry user fees in order to help the agency expedite access to generic drugs and ensure inspection parity of both foreign and domestic manufacturing sites.

GDUFA will also provide the funding needed for FDA to achieve the same surveillance inspection frequency for both domestic and foreign manufacturers to insure that all industry participants in the U.S. generic drug system are held to consistent good manufacturing practice (GMP) standards. GPhA believes the time has come to consider amending The Food, Drug and Cosmetic Act (FDCA) of 1938 to reflect the inspection model being established by GDUFA. The FDCA requires American drug manufacturers to undergo GMP surveillance inspections every two years, but it does not statutorily impose the same biennial inspection requirement on foreign facilities. This disparity should be remedied to create a level playing field for all manufacturers, foreign and domestic.

The purpose of GDUFA is to provide additional funds to FDA to supplement the traditional annual funding appropriated by Congress. The three key aims of GDUFA are:

**Safety** – Ensure that industry participants, foreign or domestic, who participate in the U.S. generic drug system are held to consistent high quality standards and are inspected biennially, using a risk-based approach, with foreign and domestic parity.

**Access** – Expedite the availability of low cost, high quality generic drugs by bringing greater predictability to the review times for ANDAs, amendments and supplements.

**Transparency** – Enhance FDA’s ability to protect Americans in the complex global supply environment by requiring the identification of facilities involved in the manufacture of generic drugs, active pharmaceutical ingredients, and improving FDA’s communications and feedback with industry in order to expedite product access.

### Overview of Performance Goals

**Application Metrics** – By year five, FDA will review and act on 90 percent of complete electronic ANDAs within 10 months after the date of submission.

**Backlog Metrics** – FDA will review and act on 90 percent of all ANDAs, ANDA amendments and ANDA prior approval supplements regardless of current review status pending on October 1, 2012 by the end of FY 2017.

**cGMP Inspection Metrics** – FDA will conduct risk-adjusted biennial cGMP surveillance inspections of generic API and generic finished dosage form manufacturers, with the goal of achieving parity of inspection frequency between foreign and domestic firms in FY 2017.

**Efficiency Enhancements** – FDA will implement various efficiency enhancements impacting review of both ANDAs and Drug Master Files (DMFs), as well as inspections, upon enactment of the program (e.g., use of complete review/response letters; completeness assessment for DMFs intending to be referenced by ANDA sponsors; division level deficiency review; and first cycle deficiency meetings for ANDAs and DMFs).

### Overview of Fees

The additional funding is an inflation-adjusted \$299 million annually for each of the five years of the program.

**Application Fees** – Include backlog fees in year 1 (for ANDAs pending review at the date of program implementation) and ANDA and Post-Approval Study (PAS) fees, as well as DMF first reference fees, in all years.

**Facility Fees** – Will be paid by both finished dosage form manufacturer and API facilities with a modest fee differential reflecting the added costs of overseas inspection.

**Source of Fees** – Fees will be derived from both applications and facilities in a 30%-70% split. Fees will be split between finished dosage form manufacturers and active pharmaceutical ingredient manufacturers in an 80%-20% split.