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GPhA: Generic Drug User Fee Act will Increase Accessibility of Generic Drugs; Urges Broad Congressional Support

WASHINGTON, D.C. (DEC. 7, 2011) — The Generic Pharmaceutical Association (GPhA) today expressed its strong support for the recently negotiated Generic Drug User Fee Act (GDUFA), the goals of which are now posted on the Food and Drug Administration's (FDA) generic drug user fee web page, which is accessible at: www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm282513.htm.

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, enhance drug quality and safety and ensure inspection parity of both foreign and domestic manufacturing sites.

"The Generic Drug User Fee Act is a milestone for the generic drug industry and a major win for American health care consumers," said Ralph G. Neas, President and CEO of GPhA. "This program, as negotiated, will result in expedited access to low-cost, high-quality generic drugs for Americans and will further safeguard the quality and accessibility of our nation's drug supply."

By the end of year five of the newly-established generic drug user fee program, the FDA will review and act on 90 percent of complete electronic ANDAs within 10 months after the date of submission (the current average approval time is 31 months), and will review and act on 90 percent of all ANDAs and ANDA prior approval supplements regardless of current review status (whether electronic, paper, or hybrid) pending on October 1, 2012 by the end of FY 2017, which effectively eliminates the current application backlog**.**

GPhA has long-maintained that in the wake of increasing globalization in drug manufacturing — nearly 40 percent of all the prescription drugs Americans take are imported, and up to 80 percent of the active pharmaceutical ingredients (API) in those drugs come from foreign sources — the FDA needs more resources to ensure adequate oversight of the nation's drug supply. Last year, the Government Accountability Office (GAO) reported that FDA was able to conduct Good Manufacturing Practice (GMP) inspections at only 11 percent of the foreign establishments in its database, compared to 40 percent of domestic sites it inspected. GDUFA will significantly improve the resources the FDA has to do this important work, ensuring that the work can be done with increasing speed but without any sacrifice to quality.

GDUFA also will 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.

Given this important development, 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.

"Through GDUFA, the generic industry has truly stepped up to the plate to do our part to help insure U.S. drug safety and establish a more level playing field among all participants in the U.S. pharmaceutical supply chain," said Neas. "In addition, this program will be of significant benefit to small businesses and first time entrants to the industry by helping to significantly reduce the time needed to commercialize a generic drug."

GDUFA calls for the generic drug industry to pay $299 million annually for five years. This funding is supplemental to what Congress appropriates to FDA each year. GPhA said the new fees have been designed to spread fees across multiple stakeholders and sources to keep individual amounts as low as possible, and are not expected to add significantly to the cost of generic drugs, so American consumers will continue to receive significant cost benefits that within the last decade have provided more than $931 billion in savings to the nation's health care system.

The three key aims of GDUFA are:

Safety — Ensuring 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 by FDA biennially, using a risk-based approach.

Access — Expediting the availability of low-cost, high-quality generic drugs by bringing greater predictability to the review times for Abbreviated New Drug Applications (ANDAs) and by ensuring more timeliness in the drug review process.

Transparency — Enhancing 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 and associated APIs, and improving FDA's communications and feedback with industry in order to expedite product access.

As previously mentioned, GDUFA includes a number of important performance metrics, chiefly that, at the end of the program's fifth year, the FDA will review and act on 90 percent of ANDAs within 10 months after the date of submission — almost 2 years faster than today's average review timetable. By that time, the FDA also 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 in order to address the significant backlog of outstanding applications. FDA also has committed to conducting biennial cGMP (current Good Manufacturing Practice) surveillance inspections of generic API and generic finished dosage form manufacturers on a risk-basis, with the goal of achieving parity of inspection frequency between foreign and domestic firms in 2017.

GPhA represents the manufacturers and distributors of finished generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals fill 78 percent of the prescriptions dispensed in the U.S. but consume just 25 percent of the total drug spending. Additional information is available at gphaonline.org.

– 30 –