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GPhA Encouraged with Initial Dialogue on User Fees

WASHINGTON, D.C., SEPTEMBER 17, 2010 – The Generic Pharmaceutical Association (GPhA) released the following statement from Gordon Johnston, Vice President for Regulatory Science, regarding today’s public meeting with the Food and Drug Administration (FDA) concerning the generic drug user fee program. Mr. Johnston was among the presenters at today’s meeting.

“Generic drug manufacturers are acutely aware of the need to get much-needed additional resources to the FDA and the Office of Generic Drugs to help handle the work associated with the review and approval of generic applications. Today’s meeting between FDA leadership and industry stakeholders to discuss a new generic drug user fee program is a critical step forward in assuring that added funding becomes available.

“We are eager to continue working with the Agency in developing a user fee program that provides increased certainty in the generic application review process. This includes assuring timely inspections and expanded opportunities for communications between industry and FDA.

“GPhA is especially delighted that FDA Commissioner Dr. Margaret Hamburg opened the meeting by pointing out that ‘generic drugs have carved out a critical role in healthcare for the 21st century...and provide affordable access to treatment for the public.’ The Commissioner added that the Agency and industry ‘hold a joint stake in moving forward to develop a solid use fee program.’ Her remarks today affirmed her commitment made at the GPhA annual meeting earlier this year to work toward a meaningful user fee program; one that will ‘help serve the FDA’s mission of protecting public health.’

“Our shared goal must be to provide more resources to the FDA so that consumers can be assured of timely access to FDA-approved, safe and effective, affordable generic medicines. GPhA is dedicated to moving forward with the Agency and industry colleagues on this critically important issue.”

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 75 percent of the prescriptions dispensed in the U.S. but consume just 22 percent of the total drug spending. Additional information is available at gphaonline.org.