FOR IMMEDIATE RELEASE
Feb. 9, 2012
CONTACT: David Belian
202-249-7124

GPhA Statement on FDA Draft Guidance on Biosimilar Product Development

WASHINGTON, D.C. (FEB. 9, 2012) – The Generic Pharmaceutical Association (GPhA) today issued the following statement in response to the Food and Drug Administration's (FDA) release of draft guidance on biosimilar product development:

GPhA is pleased that the FDA has issued draft guidance today on the development of a regulatory pathway for generic biologic drugs, or biosimilars, as it is an important step in getting these affordable, lifesaving medicines into the hands of doctors and patients.

Biologic medicines are often the only treatments for many of the most severe diseases. However, their high price tag can keep them out of reach for many patients. As proven with chemical prescription drugs, competition from generics will be the most important factor in holding down the cost of biologic medicines.

GPhA will carefully review the guidance in the coming days and prepare comments that will be publicly available. We look forward to continuing to work with the agency to ensure that a regulatory mechanism is developed that does not serve as a barrier to competition, but rather would ensure the robust competition needed to lower costs and spur future innovation.

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 –