FOR IMMEDIATE RELEASE
April 13, 2011

CONTACT: David Belian
202-249-7124

GPhA Calls on FDA to Support Supreme Court Review Of Case That Threatens Generic Competition

WASHINGTON, DC (APRIL 13, 2011) – The Generic Pharmaceutical Association (GPhA), which represents the world's leading generic drug manufacturers and suppliers, has written a letter to FDA Commissioner Margaret Hamburg urging the Agency to support Supreme Court review of *Caraco Pharm. Labs, Ltd. V. Novo Nordisk A/S*.

GPhA explained that Supreme Court review of *Caraco* is needed because the Federal Circuit's ruling in that case threatens to eliminate a critical check on brand-name drug manufacturers' ability to block generic competition by providing FDA with misleading and overbroad descriptions of their patents.

Specifically, the *Caraco* case involves the Hatch-Waxman Act's counterclaim provision, which complements "Section viii" of the act and facilitates generic competition by permitting generic drug makers to market their products for FDA-approved uses not covered by any patent. When a generic drug maker seeks marketing approval for only a drug's unpatented uses, Section viii allows FDA to grant a "carve-out" label that permits the generic to market the drug for those uses alone, thus avoiding litigation over patent infringement.

In the *Caraco* case, however, Novo thwarted FDA approval by changing its "use code," a description of the patent required to be filed by the FDA. Because FDA is not institutionally equipped to question brands' use codes by reading their patents, Novo's change prompted FDA to reject Caraco's proposed carve-out label. With this step, Novo has shown a clear path for brands to circumvent Section viii. And the Federal Circuit held that there is no judicial remedy for the problem. If the panel's ruling stands, Novo's manipulative actions will become a playbook for all brands and cost consumers millions of dollars by delaying the introduction of affordable, lifesaving generic drugs.

GPhA urges FDA to support Supreme Court review of this decision, and calls on the Agency to recommend that the Acting Solicitor General forcefully support certiorari to address this issue of great national importance.

A copy of the letter is available at http://gphaonline.org/sites/default/files/Caraco%20V%20Novo.pdf.

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.

– 30 –

Generic Pharmaceutical Association - 777 Sixth Street, NW, Suite 510 - Washington, DC 20001