GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

November 10, 2005

Ambassador Robert Portman
United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20506

Dear Ambassador Portman:

It is our understanding that the last round of the U.S. – Andean Free Trade Agreement (FTA) is fast approaching, and that during this round, the Parties intend to negotiate the intellectual property and related sections regarding pharmaceuticals. The Generic Pharmaceutical Association (GPhA) urges you to seize this opportunity to ensure a more balanced FTA than those negotiated by your predecessors. The successes of the U.S. healthcare system and U.S. pharmaceutical industry may be attributed to the tenuous balance in the structure of the U.S. pharmaceutical market that encourages true innovation while also facilitating access to affordable generic medicines. Yet, recent FTAs jeopardize this balance, allowing periods of market exclusivity and patent and other protections that exceed standards established under U.S. law—all measures that will further restrict the public's timely access to affordable medicine at home and abroad.

One of the laudable goals of the Bush administration is to increase the global sharing of drug research and development costs. In order to achieve this, other governments must rightfully relinquish strict price controls that suppress the market, and result in chilled innovation and stifled generic competition. Presently, the U.S. is the only developed nation that does not implement price controls, and as a result, it leads the world in innovation. The U.S. balances its protection of innovation with laws that allow its generic industry to thrive. Through this balance, the U.S. succeeds in sustaining vigorous innovation while simultaneously maintaining affordable access to quality medicine. However, USTR recently negotiated FTAs that increase protection of innovation, but blatantly exclude provisions to ensure affordable access. The FTAs ignore the interdependence of a robust generic industry and the promotion of innovation that has made the U.S. so successful. These unbalanced agreements do nothing to ensure affordable access to drugs for consumers and will discourage the relinquishing of price controls around the globe, ultimately undermining the goal of the administration for global R&D sharing.

Specifically, recent FTAs contain unlimited patent extensions, greater market exclusivity, and elimination of the requirement that a brand company disclose the best mode of practicing its invention: all divergences from U.S. law. The USTR should ensure that the terms of our trade agreements do not create even potential discrepancies

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with U.S. law. As negotiations for the U.S. – Andean FTA reach their conclusion, we urge USTR to correct these flaws and put the consumer interest of having access to affordable medicines on equal footing with the protection of innovation. For a more detailed discussion of these and other problematic IP provisions in recent FTAs, please refer to our letter of May 9, 2005.

Finally, recent harmonization efforts in Congress and the WTO indicate that the U.S. will continue to face pressure to adapt its laws to international standards. Yet, U.S. FTAs spur on the establishment of international pharmaceutical standards counter to our own. Expansion of intellectual property protection under international harmonization will make affordable generic medicines less available to consumers in foreign countries. And, when – not if – harmonization efforts succeed, U.S. consumers will have to wait even longer to gain access to affordable generic medicine, causing U.S. pharmaceutical expenditures to increase exponentially. For the sake of global health and the health of Americans, our trade agreements should not contribute to the establishment of greater intellectual property standards than those already provided under U.S. law.

Thank you for your consideration of our concerns.

Sincerely,

Kathleen Jaeger
President & CEO
Generic Pharmaceutical Association

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