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July 25, 2002

**Food and Drug Administration  
Dockets Management Branch  
5630 Fishers Lane  
Room 1061 – HFA-305  
Rockville, MD 20852**

**Re: Docket No. 02D-0258  
Guidance for Industry  
Bioavailability and Bioequivalence Studies for Orally Administered Drug  
Products – General Considerations**

Dear Sir or Madam:

The Generic Pharmaceutical Association (GPhA) applauds FDA's efforts to evolve the science behind the regulations governing the production and testing of pharmaceuticals to ensure their safety and efficacy. GPhA represents greater than 97% of the generic drug manufacturers who make 42% of all prescriptions written in the United States. GPhA intends to submit comments on the draft *Guidance for Industry Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations*. Given the complexity of the issue we request an extension of the comment period from 30 days to 90 days. This will provide sufficient time to have our member companies thoroughly review the draft guidance and GPhA's Technical Advisory Committee and its Biopharmaceutics Subcommittee synthesize the comments into a submission.

We appreciate your consideration of our request. Please do not hesitate to contact me as necessary.

Respectfully submitted,

Steve Bende, Ph.D.  
Vice President  
Science, Professional and Regulatory Affairs

02D-0258

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