

March 21, 2005

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

Re: Docket No. 2004D-0524
Draft Guidance for Industry
ANDAs: Pharmaceutical Solid Polymorphism;
Chemistry, Manufacturing, and Controls Information

Dear Sir or Madam:

On behalf of the Generic Pharmaceutical Association (GPhA), the following comments are submitted on the Draft Guidance for Industry ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information. GPhA represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA members manufacture more than 90% of all affordable pharmaceuticals dispensed in the United States.

GPhA is pleased that FDA continues to issue guidance to industry on important scientific issues that specifically address advice and recommendations for submission of abbreviated new drug applications (ANDA). The above referenced draft guidance provides additional information and clarification on issues related to solid polymorphism and especially the expectations for 'sameness' of the reference listed drug.

Overall, the recommendations put forth in the draft guidance appear to represent the FDA's recent practice regarding polymorphs and ANDAs. Providing additional information and clarity in the form of this guidance is encouraged.

GPhA appreciates the opportunity to comment.



Gordon Johnston
Vice President Regulatory Affairs