

January 30, 2004

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

Re: Comments on Draft Guidance for Industry on Pharmacogenomic Data Submissions [Docket No. 2003D-0497], Federal Register Notice: November 4, 2003 (vol. 68, No. 213, 62461-62463)

Dear Sir or Madam:

On November 4, 2003, the Food and Drug Administration (FDA) issued the above referenced Federal Register Notice soliciting public input on draft guidance to industry on Pharmacogenomic Data Submissions. The draft guidance provides recommendations to sponsors holding investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) on what pharmacogenomic data to submit to the agency during the drug development process, the format of submissions, and how the data will be used in regulatory decision making.

GlaxoSmithKline (GSK) welcomes the opportunity to comment on FDA's Draft Guidance. GSK is one of the world's leading research-based pharmaceutical and biotechnology companies. Our company is dedicated to discovering and developing medicines that allow patients to lead longer, happier, healthier, and more productive lives.

Advances in genetic research are now opening up new horizons in the understanding of the science behind the variability between individuals. We are using information gleaned from the human genome throughout the drug discovery and development process to identify novel ways to combat disease. GSK is actively engaged in the conduct of pharmacogenomic research to provide safer and more effective medicines.

Because of our significant interest in this topic, enclosed are specific comments submitted on behalf of GlaxoSmithKline. In addition, as members of the Pharmaceutical Research and Manufacturers of America (PhRMA), GSK has contributed to the comments on this draft guidance submitted by PhRMA and we are generally in agreement with those comments.

Our comments are provided in duplicate. If you have any questions regarding these comments, please contact me at (919) 483-6159.

Sincerely,

Susan T. Hall, Ph.D.
Director,
U.S. Regulatory Affairs