



Johnson & Johnson
PHARMACEUTICAL RESEARCH
& DEVELOPMENT

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

January 14th, 2004

Docket 2003D-0497

FDA Guidance Document on Pharmacogenomics Data Submissions

Dear Sir/Madam,

Attached you will find comments from Johnson and Johnson pharmaceutical business and research organizations regarding the Draft Guidance for Pharmacogenomic (PGx) Data Submission, published in the Federal Register November 3, 2003.

If you have any questions or concerns regarding the attachment, please feel free to contact me. We appreciate the opportunity to comment as a company and look forward to hearing from the Agency in the near future.

A hard copy of this electronic submission is forthcoming. Please confirm receipt of this electronic correspondence for our records.

Sincerely yours,

Iman Barilero, PhD, PharmD
Associate Director, European Regulatory Affairs
Global Regulatory Affairs and Quality Assurance
Johnson & Johnson Pharmaceutical Research and Development

Attachment (1)