

August 10, 2004

Briefing Document for FDA meeting

Advisors and Consultants Staff
FDA, CDER, OEP
HFD-21, Room 1093
5630 Fishers Lane
Rockville, MD 20852-1734

Re: NDA 18-936
Briefing document for public disclosure without redaction

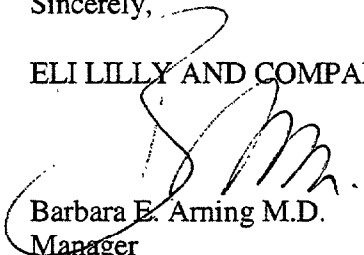
Dear Mrs. Anuja Patel,

Please find enclosed the 60 copies of Lilly's briefing document prepared for the upcoming FDA advisory board meeting on September 13 and 14, 2004. The document is available for public disclosure without redaction. You will receive an electronic copy via e-mail today as well.

Please call me at (317) 276-1489 if you require any additional information or there are any questions. Alternatively, you may contact Gregory T. Brophy, Ph.D, Director, U.S. Regulatory Affairs at (317) 277-3799. Thank you for your cooperation and assistance.

Sincerely,

ELI LILLY AND COMPANY



Barbara E. Arning M.D.
Manager
US Regulatory Affairs

cc: Mr. Paul David, R.Ph., Senior Regulatory Project Manager, FDA