



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

IND 59,588

Sorbent Therapeutics  
Attention: Mr. Donald Joseph  
750 East Bunker Court, Ste 900  
Vernon Hills, IL 60061-1863

Dear Dr. Joseph:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for Cross-Linked Polyelectrolyte.

We also refer to your April 7, 2008 request for Fast Track designation. We have reviewed your request and concluded that it meets the criteria for the Fast Track designation. Therefore, we are designating as a Fast Track development program the investigation of Cross-Linked Polyelectrolyte for reduction in morbidity and mortality in patients undergoing hemodialysis or in congestive heart failure. Please note that if the clinical development program you pursue does not continue to meet the criteria for Fast Track designation, the application will not be reviewed under the Fast Track program.

For further information regarding Fast Track Drug Development Programs, please refer to the FDA document "Guidance for Industry on Fast Track Drug Development Programs: Designation, Development, and Application Review". This document is available on the internet at <http://www.fda.gov/cder/guidance/index.htm> or may be requested from the Office of Training and Communications, Division of Drug Information at (301) 827-4570.

If you have any questions, please call Anna Park-Hong, Regulatory Project Manager at (301)796-1129.

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