

Pharmaceutical Division

Biological Products

Carol M. Moore
Vice President
Worldwide Regulatory Affairs

September 24, 2001

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

Re: Request for Extension to Submit Comments for the Draft Guidance entitled "Guidance for Industry: Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products", Docket No. 97D-0318

Dear Sir or Madam:

Bayer Corporation is requesting a two-week extension for the submission of comments on the Draft Guidance entitled, "Guidance for Industry: Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products (August 2001)", Docket No. 97D-0318. As a result of the tragic events of last week in New York, Washington, and Pennsylvania, Bayer Corporation is requesting this additional time to submit comments on this important issue.

Should you have any questions, please contact me or Dr. Mary Ann Lamb at (919) 359-7143.

Sincerely,



Carol Moore
Vice President
Worldwide Regulatory Affairs
Responsible Head

MAL/NJ

97D-0318

EXT 4

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