



PLASMA FRACTIONS FOR QUALITY BIOLOGICAL PRODUCTS

**Sera-Tec Biologicals
Limited Partnership**

Regulatory Affairs

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September 26, 2001

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

SUBJECT: Request for Extension to Submit Comments for the Draft Guidance entitled, "Guidance for Industry: Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jacob Disease (CJD) and Variant Creutzfeldt-Jacob Disease (vCJD) by Blood and Blood Products (August 2001)," Docket No. 97D-0318

Dear Sir or Madam:

Sera-Tec Biologicals is requesting an extension for the submission of comments on the Draft Guidance entitled, "Guidance for Industry: Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jacob Disease (CJD) and Variant Creutzfeldt-Jacob 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, our company is requesting this additional time to submit comments on this important issue.

Should you have any questions, please contact me at 847-270-3401. Thank you for your consideration.

Respectfully,

Roger Brinser
Senior Director, Regulatory Affairs

97D-0318

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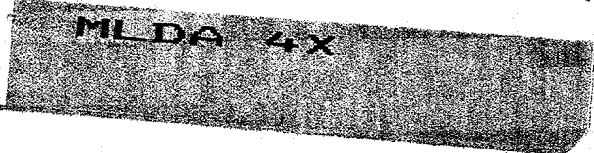
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