



8832 '01 SEP 27 11:41

September 26, 2001

Food and Drug Administration  
5630 Fishers Lane; Room 1061  
Rockville, MD 20852

Attention: Dockets Management Branch, HFA-305

RE: Reference Number FDAA01017

SUBJECT: Request for Extension to Submit Comments for the Draft Guidance entitled, "Guidance for Industry: Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products (August, 2001)," Docket Number 97D-0318.

Dear Sir or Madam:

Nabi is requesting a two-week extension for the submission of comments on the Draft Guidance entitled, "Guidance for Industry: Revised Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant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 Number 97D-0318. As a result of the tragic events of last week in New York, Washington, and Pennsylvania, industry is requesting this additional time to submit comments on this important issue.

Should you have any questions, please contact me at (561) 989-5731. Thank you for your consideration.

Sincerely,

Mary Gustafson  
Senior Director  
Regulatory Affairs/Plasma

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97D-0318

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