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THERAPEUTIC CORPORATION

28 September 2001

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Dockets Management Branch (HFA -305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Docket No. 97D-0318

Dear Sirs or Madam:

Alpha Therapeutic Corporation is providing the following comments relative to the Draft Guidance entitled, "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfield-Jakob Disease (vCJD) by Blood and Blood Products (August 2001)."

1. Donor Screening

Alpha feels that it would be helpful to provide guidance on the "appropriate counseling" of donors at an increased risk for CJD.

Alpha advocates that the "Recommended Questions to Identify Donors at Risk for exposure to BSE" be coordinated to coincide with SPE screening at four-month intervals.

2. Post Donation Information

Additional questions regarding donor travel are to be included in the screening process. As a result of these new questions, some currently qualified donors may be deferred. Language in the guidance suggests that lookbacks and BPDRs will be required as a result of this additional screening. Alpha advocates that retrospective lookbacks or BPDRs are not necessary since the current scientific evidence does not support that CJD or vCJD is transmitted by blood transfusion in humans. Additionally, implementation of new screening questions and information obtained in response to them is not an unexpected and unforeseeable event as it

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relates to previously qualified donors. Alpha advocates a prospective quarantine beginning after 31 May 2002. This approach would be similar to FDA recommendations used when implementing testing for anti-HCV.

3. Plasma Derivatives

Alpha does not advocate the withdrawal of pooled plasma, intermediates, or plasma derivatives manufactured from donors with CJD or CJD risk factors, or exposure to vCJD.

4. Military deferrals

It appears that the rationale for military associated deferrals is based on shipments of British beef and not exposure years. Alpha advocates a thorough review of proposed military deferral criteria and a possible revision if supported by a meaningful review of exposure years.

5. Clarification

Please clarify the wording "as soon as possible" on page fifteen of the Draft Guidance. BPDR's currently must be reported within 45 days of discovery. Is this time frame acceptable?

6. Vegetarians

Will FDA exclude strict vegetarians from the vCJD deferral process?

Alpha Therapeutic Corporation appreciates the opportunity to comment on this draft guidance.

Respectfully,

Paul Novikoff

Paul Novikoff
Manager, Regulatory Affairs

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