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03 March, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852-1448

Re: Docket number: 99D-4577

To Whom It May Concern:

Staff members of Alpha Therapeutic Corporation have reviewed the Draft Guidance for Industry, Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma and have the following comments:

1. II. INTRODUCTION: Add "or plasma" to the second sentence – "To date, there are no approved nucleic acid tests for blood <or plasma> donor screening..."
2. III. BACKGROUND: Add "or plasma" to the second sentence in the sixth paragraph – "Neither this test, nor any other nucleic acid test, has been approved by FDA for blood <or plasma> donor screening to date."
3. IV. REGULATORY CONCERNS:
 - 3.1. Section B: Additional guidance and insight into what FDA expects as evidence that the "...mechanism for identifying positive units and notifying donors" has been adequately validated would be helpful. For example, can the mechanism be validated as a part of the pooling system without being validated independently? Such insight should preclude numerous questions from industry asking for clarification.

Please call Kurt Carlson at (323) 227-7083, or me at (323) 227-7558, if you have any questions in this regard.

Sincerely yours,

Michael Dubinsky
Director
Source Plasma Regulatory Affairs and Compliance

99D-4577

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