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July 11, 2005

Ms. Brenda R. Fried
Center for Biologics Evaluation and Research
FDA
1401 Rockville Pike Suite 200N
Rockville, MD
20852-1448

**RE: Draft guidance "Toxicity Scale for Healthy Adult and Adolescent Volunteers
Enrolled in Preventive Vaccine Clinical Trials"**

Dear Ms. Friend:

Please accept the following comments regarding the above referenced draft guidance specific to Table B (Laboratory abnormalities):

- 1) Question the Mild (grade 1) hyperglycemia value - This appears as normal in most all ranges
- 2) There are 2 listings for "hypocalcemia" - it appears that the second one should be hypercalcemia.
- 3) Alkaline phosphate, severe (grade 3) lower value should begin at 3.1

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Rexann G. Pickering".

Rexann G. Pickering, Ph.D., R.N.
Human Protection Administrator
Methodist Healthcare Institutional Review Board

2005D-0155

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