



Our Reference: BL 125488/0

Instituto Bioclon, S.A. de C.V.
Attention: Ms. Jennifer Spinella
Rare Disease Therapeutics, Inc.
9550 Cuyamaca Street, Suite 203
Santee, CA 92071

Dear Ms. Spinella:

Attached is a copy of the memorandum summarizing your November 21, 2013 late-cycle meeting teleconference with CBER. This memorandum constitutes the official record of the meeting teleconference. If your understanding of the meeting teleconference outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER as soon as possible.

If you have any questions, please contact Edward Thompson at (301) 827-9167.

Sincerely yours,

Basil Golding, MD
Director
Division of Hematology
Office of Blood Research and Review
Center for Biologics
Evaluation and Research