DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, Maryland 20857

JUN 4 2009

By Facsimile: (719) 635-4576

Scott J. Mikulecky, Esq.
Sherman & Howard, L.L.C.
90 S. Cascade Avenue, Suite 1500
Colorado Springs, CO 80903

Re: Coast IRB, LLC

Dear Mr. Mikulecky:

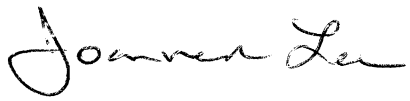
The Food and Drug Administration (FDA or the Agency) is sending you this letter in follow up to the June 1, 2009 telephone conversation between you and other representatives of Coast IRB, LLC and FDA concerning the operations of your client, Coast IRB, LLC. During that telecon, Coast updated the agency on its transition process and notified FDA that it intends to cease all operations as of June 30, 2009.

While we appreciate the advanced notice that you plan to cease operations at the end of the month, we are concerned by the number of studies that have not yet been transferred to a new IRB. FDA encourages Coast to work diligently with study sponsors and the new IRBs to ensure the expeditious transfer of any remaining studies. It is critical that the on-going studies be reviewed and approved by new IRBs by June 30th to avoid a possible interruption in the research.

As requested by FDA, Coast has been maintaining a listing of the final disposition of all studies under its jurisdiction, including the name of the new IRB and the date of transfer. Again, we understand that Coast intends to cease operations and would like to remind you that FDA will need a complete list of the final disposition of all studies before Coast ceases operations. FDA recognizes that due to disclosure issues, the new IRB may not be able to notify Coast of the review decision made (i.e., approval, disapproval, or require modifications in order to secure approval). The agency would like to clarify that, although we do not need to know the substance of the IRB's decision, we do need to be informed that the review by the new IRB has occurred, a decision by the new IRB has been reached, and the date of that decision.

Please continue to keep us apprised of the status of the study transfers. If FDA can assist you in any way, or if you have any questions, please feel free to contact me at 301-827-1256 or Kevin Prohaska, D.O., M.P.H., at 301-796-3707.

Sincerely,



Joanne R. Less, Ph.D.
Director
Good Clinical Practice Program
Office of the Commissioner
Food and Drug Administration