DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via UPS

October 7, 2010

Our Reference # 3007575901

Trent Arsenault, Directed Donor
38068 Canyon Heights Drive
Fremont, CA 94536

Dear Mr. Arsenault:

We are in receipt of your recent letter dated October 1, 2010 regarding your request for an extension until December 1, 2010 to file a response to the Inspectional Observations, Form FDA-483, issued to you at the close of the most recent FDA inspection. There is presently no timeframe for a response to an FDA-483 as it is not required for an inspected entity to respond to an FDA-483.

There is currently a pilot program in place to facilitate compliance activities, when a warning letter is contemplated in response to inspectional observations. Under the pilot program, the inspected entity has 15 working days from issuance of the 483 to respond or the FDA can issue the warning letter without taking their response into consideration. The link to the Federal Register notice regarding this pilot program is http://edocket.access.gpo.gov/2009/pdf/E9-19107.pdf.

If you cannot respond to all of the FDA-483 observations within the 15 working days, I encourage you to submit a partial response as soon as possible, particularly if you have additional documents or procedures for the agency to review. Following your initial response, you may continue to submit responses and documentation; however, be reminded that any responses made after 15 business days from the close of the inspection may not be considered by the agency in making a determination as to whether to move forward with an enforcement action.

Sincerely,

Steven R. Stramba

For Barbara J. Cassens
District Director
San Francisco District
U. S. Food and Drug Administration