

October 1, 2010

Barbara Cassens, Director  
Food and Drug Administration  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070

RE: Inspection Form 483 Response - FEI Number 3007575901

Dear Mrs. Cassens,

I wanted to remark on the professional and courteous attitude of Investigator Sandhu, Investigator Velasquez, and Investigator Diaz during their inspection from 8/27/2010 - 9/20/2010. I enjoyed meeting them.

As mentioned to Investigator Sandhu, the inspection period occurred simultaneously with my promotion to a new position at my employer, HP, to consult with Bank of America on the IP architecture and network security of Bank of America's corporate network. HP signed a contractual agreement with Bank of America this year, and I was selected for my role to provide immediate expertise during a critical transitional period with Bank of America and integration of a large financial institution. I worked throughout the duration of the inspection to balance the FDA appointments along with the demands of my employment and also a re-location of my office, and I thank Investigator Sandhu for her understanding for arranging meetings that agreed with our schedules.

In order to complete location of additional paperwork which I think will be very helpful to my response as well as submit data that I was not able to provide to Investigator Sandhu, I am requesting the FDA consider my employment circumstance and allow me until December 1st, 2010 or sooner to provide my response to form 483. I understand that normal response timeframe is within 15 days of inspection, however this extension would be extremely valuable to provide me sufficient timeframe to respond as well as continue to meet obligations during a critical deployment schedule at Bank of America. If there is any concerns to the length of this extension, I would appreciate if I could be contacted or told if there is another date that I could respond by.

Best Regards,

Trent Arsenault  
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Fremont, CA 94536  
(925) 484-4378