



Handwritten notes: "3008058540 LM 10/11", "DIB #", "10/14/11", "REF MBT", "cc: BCF".

October 10, 2011

FDA Florida District  
555 Winderly Place  
Suite 200  
Maitland, FL 32751

RE: InfuPharma LLC

To Whom It May Concern:

We are submitting the attached action plan stating how InfuPharma will address the concerns mentioned in the report we received on September 27, 2011.

Writing new policies and procedures and implementing them is a time-consuming process that I am sure you can appreciate cannot be completed in the 15 days allotted to respond to your report. However, attached are drafts of SOPs that are currently being reviewed and revised. Once they have been approved they will be implemented and we will have a series of training and in-service to ensure that all staff is aware of the changes and begins to follow them immediately.

We intend to have these new policies and procedures fully implemented within 90 days of *this* letter.

Also attached please see the supporting documentation that was requested in regards to our balance.


We have hired a Quality Assurance director. We believe her qualifications make her a wonderful fit for this position and that she will be an integral part in implementation and continued compliance with the steps we are taking.

If you have any questions please feel free to contact me directly.

RECEIVED

OCT 18 2011

COMPLIANCE

Sincerely,  
  
Michel Rizo, PharmD  
President