

To: Mary A. Malarkey, Director, Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research (CBER)
1401 Rockville Pike, HFM-600
Rockville, MD 20852
Delivery Via Fedex Overnight: 794157012888

RE: Order to Cease Manufacturing

28-Nov-2010

Dear Ms. Malarkey,

Thank you for taking the time to meet with me via phone on the Friday before Thanksgiving.

It has come to my attention that CBER is seeking information regarding my sexual intimacy. I appreciate the interest.

In the November 1st letter (attached), the letter in which a hearing was requested, reference was made to certain written information, with the intention that this information is to be presented upon request, in an informal manner, or relied upon in accordance with a Part 16 proceedings, as explained in Part 16:

- 16.24 (g) "FDA and the party requesting the hearing will, if feasible, at least 1 day before the hearing provide to each other written notice of any published articles or written information to be presented at or relied on at the hearing."
- 16.60 2(c) "The hearing is informal in nature, and the rules of evidence do not apply."

As the hearing date approaches, I plan to work closely with you and Ms. Lenkel, Director, Office of the Ombudsman, regarding this and additional written information and published articles to be presented or relied upon at the proceedings.

Finally, in the letter today to Dr. Hamburg, Commissioner of the FDA, it is mentioned several families have voiced concern regarding the cease manufacturing order and their ability to have additional children in the future. Please consider the existing children in these small families who may be denied a biological sibling, and the parents, who have planned their lives with the intention to have more than one child. These young children, as described by their parents, are growing up to be strong and bright individuals, and it is realistic to imagine the outcome of upcoming decisions would have an impacting influence on their lives.

Best Regards,



Trent Arsenault