To: Barbara Cassens and Mary Malarkey, Directors, FDA -- Hand Delivered --
RE: Response to Form 483 and "Order to Cease Manufacturing"

01-Nov-2010
Dear Ms. Cassens and Ms. Malarkey,

50 individuals and their families met with me since 2006 wanting me to be the biological father of their child. They often contact me through Facebook or the internet. 11 babies have been reported born. Most of these families live in the San Francisco area. The mothers have sent photos of the children; none have introduced me to the children yet. Several of the mothers asked me to be available again as a biological father for a 2nd child. My job at Hewlett-Packard has required me to be located in the Bay area for the last 10 years. I have never been employed in the medical profession nor do I have any type of college degree.

The FDA visited me at my apartment home where I live alone in Fremont, CA to inspect. I registered at the FDA's request and my home is where sperm is "manufactured" in my body.

Following the inspection, the FDA replied to my request for additional time to find paperwork. I have located written statements signed by myself and the females who met with me declaring that we are sexually intimate partners (abbreviated "SIP" hereafter) of each other with the understanding that a SIP may not also be a directed donor. This information is available to be viewed upon request. In addition, all new females who have met with me after the close of the FDA's inspection on 20-Sep-2010 have also indicated in signed written statements that they are a SIP to me with the understanding that a SIP may not also be a directed donor.

If the FDA requests registration (FEI 3007575901) renewal in December, individual SIP status will be indicated.

Finally, California and other states recently legally recognize certain non-traditional types of marriages, which can involve non-traditional sexual intimacy when trying to have a baby. The FDA does not define "sexually intimate" when publishing their "guidance". In light of recent events that portray the challenges that people in these non-traditional groups face, I ask that the FDA would not offer them yet another challenge if attempting to re-interpret these families' meaning of the term "sexually intimate". Should the FDA decide SIP partners' reproductive lifestyle "choice" is unsatisfactory response to a "cease manufacturing" order, then, as affected partners, this will be interpreted as an order against all 50 SIPs. The option to hearings in San Francisco would be requested, where myself and these families would have the opportunity to speak before the FDA.

Page 2 contains final responses to Form 483 Observations following the inspection.

Best Regards,

Trent Arsenault

Observation # 1-4, & 6 Response:

Per USC Sec 1271.90 (a) & (a2):

> (a) You are not required to make a donor-eligibility determination under 1271.50 or to perform donor screening or testing under 1271.75, 1271.80 and 1271.85 for... (a2) Reproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use.

Observation # 5 Response:

As evidenced in the adhesive sticker provided to FDA Consumer Safety Officer Sandhu on 8/27 and as declared in the affidavit dated 9/16, accompanying records of the human cell tissue products (HCT/P's) for the SIP's matches USC Sec 1271.90 (b2) & (b3) :

> (b) You must prominently label an HCT/P described in paragraph (a) of this section [(1271.90 a2) ...donated by a sexually intimate partner...] as follows: (b2) "NOT EVALUATED FOR INFECTIOUS SUBSTANCES," (b3) Unless the HCT/P is for autologous use only, "WARNING: Advise recipient of communicable disease risks," (i) When the donor-eligibility determination under 1271.50(a) is not performed or is not completed.

--End of Responses--

Additional attachments:

- **FDA's Reply to Request for Extension of FDA Form 483**
- **FDA's From 483 Inspection Observations**
- **FDA's Form 463a Signed Affidavit**
- **FDA's Order to Cease Manufacturing of HCT/Ps**