DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 7, 2011

Via Hand Delivery

Ms. Laurie Lenkel, J.D.
FDA Ombudsman
Hearing Coordinator
Office of Scientific Integrity
Bldg. 32, Room 4262
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Order to Cease Manufacturing of HCT/P's – Trent Arsenault's Request for a Hearing

Dear Ms. Lenkel:

Enclosed you will find CBER's Motion to Deny Mr. Arsenault's Request for a Hearing and for Administrative Summary Judgment with accompanying memorandum in support of the motion. Please file these in the above-referenced matter.

As indicated below, I have provided these materials to Mr. Arsenault.

Sincerely,

Denise Zavagno
Counsel for the Center for Biologics
Evaluation and Research
Associate Chief Counsel for Biologics

cc: Mr. Trent Arsenault
via UPS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

IN THE MATTER OF TRENT C. ARSENAULT 38068 Canyon Heights Drive Fremont, California 94536	Docket No.

CBER'S MOTION TO DENY
TRENT ARSENAULT'S REQUEST FOR A HEARING
AND FOR ADMINISTRATIVE SUMMARY JUDGMENT

The Center for Biologics Evaluation and Research (CBER) moves to deny Mr. Trent Arsenault's request for a hearing, and respectfully states:

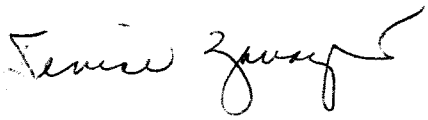
1. On November 1, 2010, CBER ordered Mr. Arsenault, under 21 U.S.C. 1271.440(a)(3), to cease manufacturing HCT/Ps (human cells, tissues, and cellular and tissue based products). Mr. Arsenault's firm recovers and distributes semen and therefore is a manufacturer of HCT/Ps. 21 CFR 1271.3(d). FDA determined that because Mr. Arsenault is in violation of 21 CFR Part 1271, Mr. Arsenault does not provide adequate protections against the risks of communicable disease transmission through the use of these HCT/Ps.

2. Mr. Arsenault requested a hearing under 21 CFR 1271.440(e) in accordance with 21 CFR Part 16. Mr. Arsenault submitted his request for a hearing on November 1, 2010. Because Mr. Arsenault requested a hearing, the Order will be effective after a decision in, and in accordance with those proceedings.

3. CBER moves for denial of Mr. Arsenault's request for a hearing under 21 CFR § 16.26(a), because the materials submitted by Mr. Arsenault in support of his hearing request fail to raise a genuine and substantial issue of fact justifying a hearing.

4. Additionally, CBER moves for administrative summary judgment under 21 CFR 16.26(a) on the grounds that undisputed facts of record support CBER's order to Mr. Arsenault to cease manufacturing HCT/Ps as a matter of law. A memorandum in support of this motion is attached.

Respectfully submitted,



Denise Zavagno
Counsel for the Center for
Biologics Evaluation and Research

Date: February 7, 2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

IN THE MATTER OF TRENT ARSENAULT 38068 Canyon Heights Drive Fremont, CA 94536-1810	)	Docket No.

MEMORANDUM IN SUPPORT OF CBER'S MOTION TO DENY TRENT ARSENAULT'S HEARING REQUEST AND FOR ADMINISTRATIVE SUMMARY JUDGMENT

The Food and Drug Administration (FDA), under 21 CFR Part 1271, requires that human cells, tissues, and cellular and tissue based products (HCT/Ps), including semen for artificial insemination, be manufactured in a manner that prevents the introduction, transmission, and spread of communicable diseases. Manufacture means, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening and testing of the cell or tissue donor. 21 CFR 1271.3(e). On November 1, 2010, FDA ordered Mr. Trent Arsenault to cease manufacturing HCT/Ps due to his establishment's significant violations of 21 CFR Part 1271. Mr. Arsenault has challenged FDA's Order by requesting a hearing under 21 CFR Part 16. As explained below, the Commissioner should deny this request for a hearing because Mr. Arsenault's has failed to raise any genuine and substantial issue of fact.

In deciding whether to grant a hearing, the Commissioner is presented with three straightforward issues:

- Mr. Arsenault has repeatedly admitted (during an FDA inspection, in an affidavit, in the directed donor agreements collected during the FDA inspection, and on his website) that he is a directed semen donor.[1] As a result, he is a directed donor of reproductive HCT/Ps. His records also indicate that he has failed to perform required donor eligibility determinations for a directed donor by way of donor screening and testing for all semen donations.[2] Despite this evidence, should Mr. Arsenault be granted a hearing on whether CBER properly issued to Mr. Arsenault an Order to Cease Manufacturing HCT/Ps?
- Although Mr. Arsenault admits he is a directed semen donor requiring him to follow donor eligibility requirements,[3] after CBER issued its Order, Mr. Arsenault claims to have located written statements from fifty (50) women to whom he has donated, declaring that Mr. Arsenault is a sexually intimate partner. Donor eligibility determinations are not required for reproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use.[4] FDA has [repeatedly] requested Mr. Arsenault to provide such documentation. Rather than producing these documents, Mr. Arsenault has explained that such documents are available to be viewed

[1] A directed reproductive donor is defined in 21 CFR 1271.3(l) as a donor of reproductive cells or tissue (including semen, oocytes, and embryos to which the donor contributed the spermatozoa or oocyte) to a specific recipient, and who knows and is known by the recipient before donation. The term directed reproductive donor does not include a sexually intimate partner.
[2] Under FDA regulations, a donor eligibility determination is required for directed donations of reproductive tissue. 21 CFR 1271.50.
[3] Donor eligibility requirements are found at 21 CFR 1271, Subpart C.
[4] 21 CFR 1271.90(a)(2).

upon request. Do Mr. Arsenault's allegations that he has such documents, without producing the written statements, raise a genuine and substantial issue of fact, justifying a hearing?

- As stated above, FDA regulations at 21 CFR 1271.90 provide an exception from the requirement of making donor-eligibility determinations under 21 CFR 1271.50 or to perform donor screening or testing under 1271.75, 1271.80, and 1271.85, for reproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use. Mr. Arsenault alleges that because FDA does not define "sexually intimate", non-traditional families can interpret the term "sexually intimate" to apply to their reproductive lifestyle "choice." This interpretation of the donor eligibility regulations differs greatly from FDA's plain reading of the regulations. Does Mr. Arsenault's assertion that FDA is interpreting its own regulation improperly raise any genuine and substantial issues of fact to justify a hearing?

Essentially, Mr. Arsenault wants the Commissioner to evaluate his submission and determine that he has raised a genuine and substantial issue of fact giving rise to a hearing under 21 CFR Part 16, and by way of this hearing, determine that the Order was improperly issued because Mr. Arsenault is in compliance with the requirements of 21 CFR Part 1271.

ARGUMENT

Mr. Arsenault, by his own admission, a directed semen donor since October 2006, has consistently failed to determine adequate and appropriate donor eligibility when manufacturing semen for artificial insemination. Because Mr. Arsenault in his submission has not raised any genuine and substantial issue of fact regarding these failures, a hearing is not justified. The Commissioner should deny the hearing request under 21 CFR 16.26(a) and enter administrative summary judgment on the grounds that the undisputed facts support CBER's Order to Cease Manufacturing HCT/Ps issued to Mr. Arsenault.

A. Policy Or Legal Questions Do Not Warrant An Evidentiary Hearing

Part 16 authorizes the Commissioner to deny a hearing request and resolve any legal or policy issues if the Commissioner determines that the submission of the person requesting the hearing does not raise any genuine or substantial issues of fact. The preamble to section 16.26(a) explains that the primary purpose of a Part 16 hearing is to resolve factual issues. 53 Fed. Reg. 4614 (Feb. 17, 1988). Issues of law and policy surrounding Mr. Arsenault's operation can be resolved by the Commissioner without a hearing under the applicable statutory provisions, regulations, and policies. FDA has stated that an evidentiary hearing, when there is no genuine and substantial issue of fact at issue, would result in "inefficient use of agency resources." 51 Fed. Reg. 43,217, 43,218 (Dec. 1, 1986).

Under section 16.26(a), "the person requesting the hearing" under Part 16 bears the burden of producing "information . . . to show that there exists a genuine and substantial issue of fact." 53 Fed. Reg. 4,613, 4,614 (Feb. 17, 1988). In Pineapple Grower's Ass'n of Hawaii v. FDA, cited in the proposed rule creating the hearing denial procedure at section 16.26(a),

the Ninth Circuit stated that a petitioner seeking an evidentiary hearing before FDA

> must raise 'issues.' The issues must be material to the question involved; that is the legality of the order attacked. They may not be frivolous or inconsequential. Where the objections stated and issues raised thereby are, even if true, legally insufficient, their effect is a nullity and no objections have been stated. Congress did not intend the governmental agencies created by it to perform useless or unfruitful tasks.

673 F.2d 1083, 1085 (9th Cir. 1982).

Evidentiary hearings under Part 16 are not meant to resolve issues of law or policy; on the contrary, such hearings are only intended to resolve disputes pertaining to genuine and substantial facts. In promulgating section 16.26(a), FDA declared, "If a genuine and substantial issue of fact has not been shown to exist, any remaining issues of law and policy surrounding an agency action or proposed action are not matters to be resolved in a fact-finding hearing." 53 Fed. Reg. at 4,614 (emphasis added). Thus, if a person requesting a hearing fails to present genuine and substantial facts indicating the need for a hearing -- and instead presents arguments of law or policy -- the Commissioner should deny the hearing and rule on the matters of law or policy without delay.

B. Mr. Arsenault's Noncompliance Resulted in CBER Properly Issuing the Order to Cease Manufacturing

Under the authority of section 361 of the Public Health Service Act, FDA has promulgated the regulations at 21 CFR Part 1271 for the manufacture of HCT/Ps to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps. Human semen meets the definition of an HCT/P. 21 CFR 1271.3(d).[5] Mr. Arsenault maintains a website through which he offers his semen for donation[6], and is currently registered with FDA as an HCT/P establishment that recovers semen. (Exhibit 1, Form 3356, dated December 31,

[5] 21 CFR 1271.3(d) provides that HCT/Ps "means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to...semen or other reproductive tissue."

2009). On the registration form, Mr. Arsenault reports that he recovers semen from a directed donor. In addition, in box 9 of the registration form, Mr. Arsenault indicates his title is "Directed Donor".) Between August 27 and September 20, 2010, FDA inspected Mr. Arsenault, a manufacturer[7] of reproductive tissue, to assess his compliance with these FDA regulations.

At the conclusion of the inspection, the FDA investigator issued an FDA - Form 483, Inspectional Observations. (Exhibit 2, FDA- Form 483). The FDA investigator observed, among other things, that since Mr. Arsenault began manufacturing reproductive HCT/Ps in December 2006, he had repeatedly failed to conduct donor eligibility determinations for himself, the sole directed donor, as required by 21 CFR Part 1271, subpart C. Specifically, he failed to test and screen for evidence of relevant communicable diseases, such as Human Immunodeficiency Virus, Hepatitis C Virus, and syphilis (Exhibit 2, FDA-Form 483, Observation #1, #2, #3, and #4). Mr. Arsenault also failed to conduct testing for relevant cell-associated communicable diseases, including Human T-lymphotropic virus type I and Human T-lymphocyte virus, type II (Exhibit 2, FDA-Form 483, Observation #4).

On the basis of the inspectional findings and lacking an adequate response to the FDA Form- 483, FDA determined that Mr. Arsenault was in violation of Part 1271 and failed to provide adequate protections against the risks of communicable disease transmission through the use of the recovered semen. On November 1, 2010, FDA notified Mr. Arsenault by telephone and on November 2, 2010, hand delivered to Mr. Arsenault, an Order to Cease Manufacturing of HCT/Ps because Mr. Arsenault had failed to provide adequate protections against the risks of communicable disease transmission. (Exhibit 3, Order to Cease

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[6] See, www.trentdonor.com.

Manufacturing of HCT/Ps – Mr. Trent Arsenault (Order)). Section 21 CFR 1271.440(a)(3) authorizes FDA to order an establishment to cease manufacturing until compliance with Part 1271 regulations has been achieved. The Order is effective either after the passage of five working days, or if Mr. Arsenault requested a hearing, after a decision in and in accordance with the hearing. The Order also advised Mr. Arsenault that he could request a Part 16 hearing. (Exhibit 3, Order, page 4).

FDA regulations and the Order provided Mr. Arsenault with five working days of receipt to request a hearing, or until November 9, 2010. Mr. Arsenault explained to FDA, Center for Biologics Evaluation and Research (CBER), and then to Ms. Laurie Lenkel, hearing coordinator, that he was requesting a hearing but needed additional time to submit additional materials. Both CBER and Ms. Lenkel agreed to an extension. The email from Ms. Lenkel is attached. (Exhibit 4). The email, as well as a follow-up call from CBER to Mr. Arsenault (Exhibit 5), reminded Mr. Arsenault that under Part 16, a hearing would only be held if the materials submitted raised a genuine and substantial issue of fact. Mr. Arsenault forwarded his hearing request to the FDA District Director, Ms. Barbara Cassens, and Ms. Mary Malarkey, Director of the Office of Compliance and Biologics Quality (OCBQ), CBER, on November 1, 2010, (Exhibit 6, Hearing Request), and to Dr. Margaret Hamburg, FDA Commissioner on November 28, 2010 (Exhibit 7, Hearing Request to Dr. Hamburg). He forwarded these supposed additional materials in a letter to Ms. Malarkey, OCBQ, CBER, on November 28, 2010. (Exhibit 8, November 28, 2010 letter), which simply referenced certain written information, without providing it.

[7] The inspection confirmed that Mr. Arsenault's operations meet the definition of manufacture. (See 21 CFR 1271.3(e)).

C. Mr. Arsenault Has Failed To Raise A Genuine And Substantial Factual Issue As To Whether CBER Properly Issued the Order to Cease Manufacturing

The Order to Cease Manufacturing advises Mr. Arsenault that he is significantly noncompliant with federal regulations at 21 CFR Part 1271, particularly with respect to determining donor eligibility. Mr. Arsenault, in his request for a hearing, fails to address his noncompliance, instead asserting for the first time, that he has located written statements declaring he is the sexually intimate partner with the women to whom he has donated. (Exhibit 6, Hearing Request, page 1). Further, on page 2 of the Hearing Request, he responds to the FDA 483-Observations #1-6, by asserting that the regulations do not apply because of his status as a sexually intimate partner of the recipients. (Id. page 2). Because Mr. Arsenault has raised mere allegations and fails to provide any support for this assertion, his request for a hearing must fail.

1. Requirement to Determine Donor Eligibility:

Mr. Arsenault claims that he is exempt from complying with donor eligibility requirements because he explains, "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." (Id., page 1). Mr. Arsenault further counters that "FDA does not define 'sexually intimate' when publishing 'their guidance.'" He asks that "FDA would not offer [non-traditional groups] yet another challenge if attempting to re-interpret these families' meaning of the term 'sexually intimate'." Id.

In forwarding this argument, Mr. Arsenault ignores the evidence he provided FDA investigators during the recent inspection as well as information he, himself, has submitted to

FDA. The evidence clearly indicates that he is directed donor. The evidence includes his Registration and Listing with FDA (Exhibit 1), an Affidavit signed during the recent inspection (Exhibit 9, Affidavit), copies of donor agreements collected during the inspection (Exhibit 10, Donor Agreements), and his own website. (Exhibit 11, Copies of web pages collected during inspection).

Mr. Arsenault also would have us understand that the reason FDA exempted sexually intimate partners somehow applies to his practice and an expanded non-traditional definition of the term "sexually intimate." This simply is not the case. FDA explained when promulgating the donor eligibility requirements, in the preamble to the final rule, *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products*, 69 Fed. Reg. 29786 (May 25, 2004),

> the compliance expectations for a small medical practice that provides artificial insemination are commensurate with the communicable disease risks associated with its activities. If the practice is limited to artificial insemination using either semen from an anonymous or directed reproductive donor obtained from a semen bank (§ 12 71.15(d)), or semen recovered at the practice and immediately used to inseminate the donor's sexually intimate partner (§ 1271.15(e)), then the risks are minimal and the practice is not required to comply with part 1271.

Id. at 29790.

In other words, FDA exempted sexually intimate partners because insemination with the semen from a sexually intimate partner entails minimal risks. As FDA further explained in the preamble to the proposed rule, *Suitability Determination for Donors of Human Cellular and Tissue-Based Products*, 64 Fed. Reg. 52696 (September 30, 1999),

> The second situation in which FDA is recommending but not requiring testing is for reproductive cells or tissue donated by a sexually intimate partner of the recipient. In this case, the recipient will likely have been routinely exposed to the donor's semen or other body fluids. Although some screening and testing of the donor and recipient may be appropriate, FDA believes that this should

be the responsibility of the attending physician and the donor and the recipient.

Id. at 52707.

This clarification is in sync with the plain meaning of the words, which do not require further explanation. FDA exempted sexually intimate partners with the understanding that such partners would not need to be follow donor eligibility requirements because they would already have been exposed to communicable disease risks. Accordingly, Mr. Arsenault's attempts to fit within this exemption must fail. Moreover, FDA is not "offering [non-traditional] families another challenge." Instead, FDA is protecting such "families" from communicable diseases. It is Mr. Arsenault who is offering such non-traditional "families" a challenge by attempting to circumvent the protections afforded such "families" and attempting to circumvent the requirement that semen donors be eligible donors.

Mr. Arsenault has failed to raise any genuine and substantial issues of fact regarding his failure to perform testing for relevant communicable diseases to determine donor eligibility as required by 21 CFR Part 1271. He has not rebutted the facts presented in the Order, but has instead disputed FDA's application of its own regulations. As explained above, issues of law and policy do not justify a fact finding hearing. Mr. Arsenault's arguments regarding his failure to conduct required donor eligibility testing do not justify a Part 16 hearing.

2. Compliance with Donor Eligibility Regulations :

In his hearing request, Mr. Arsenault raises no genuine and substantial issues of fact about his compliance with donor testing and screening that would render a hearing necessary. Instead, Mr. Arsenault demonstrates through his own admissions, in numerous ways, that

CBER properly issued the Order to Cease Manufacturing. CBER explains below that the evidence collected by the FDA investigator demonstrates that Mr. Arsenault, as the establishment responsible for donor testing, 21 CFR 1271.150(c)(iii), and the establishment that performs donor screening, fails to meet donor eligibility requirements and does not provide adequate protections against the risks of communicable disease transmission.

First, documents collected during the recent inspection indicated that Mr. Arsenault failed to test a donor specimen for relevant communicable diseases as required by 21 CFR 1271.80(a) and (c). For example, although a blood specimen for testing was collected on several occasions, the testing performed did not include all required communicable disease agents specified in 21 CFR 1271.85. (Exhibit 12, Testing Records). The chart below summarizes the date testing was performed and Mr. Arsenault's failure to perform all required testing for communicable diseases. Additionally, Mr. Arsenault has failed to provide any evidence that the tests used were FDA-licensed, approved or screened tests as required by 21 CFR 1271.80(c).

Date	Required disease not tested for
10/04/2006	Hepatitis B, Hepatitis C, HTLV Type 1 and 2, CMV and HIV Type 2
12/18/2006	Hepatitis B, HIV Type 1 and 2, Syphilis, HTLV Type 1 and 2, Chlamydia, Gonorrhea, CMV
01/21/2008	Hepatitis B, Hepatitis C, HIV Type I and 2, HIV Group 0, HTLV Type 1 and 2, CMV
12/29/2008	HIV Group 0, HTLV Type I and 2, CMV
05/05/2009	Hepatitis B, Hepatitis C, HIV Type I and 2, HIV Group 0, Chlamydia, Gonorrhea

Second, documents collected during the recent inspection indicate that Mr. Arsenault failed to test himself, the sole donor of viable, leukocyte-rich cells or tissue to adequately and appropriately reduce the risk of transmission of relevant cell-associated communicable diseases, as required by 21 CFR 1271.85(b) and 21 CFR 1271.80(c). For example, the testing on the blood specimens collected on 10/04/2006, 12/18/2006, 01/21/2008, and 12/29/2008,

failed to include testing for all required cell associated communicable diseases including Human T-cell Lymphotropic Virus types I and II (HTLV-I/II) and cytomegalovirus. (Exhibit 12, Testing Records). Further, there is no evidence that testing on specimens for cell-associated communicable diseases was performed using FDA-licensed, approved or cleared donor screening tests.

Third, the documents collected during the recent inspection indicate that Mr. Arsenault, as the establishment responsible for donor testing (21 CFR 1271.150(c)(iii)), failed to test the donor specimen from himself, the sole donor of reproductive cells or tissue, to adequately and appropriately reduce the risk of transmission of relevant communicable diseases of the genitourinary tract, including Chlamydia trachomatis and Neisseria gonorrhea. See 21 CFR 1271.85(c); 21 CFR 1271.80(c). The testing records collected indicate that the testing performed on 12/18/2006, and 05/05/2009 did not include testing for these communicable diseases of the genitourinary tract as required by 21 CFR 1271.85(c) and 1271.80(c) (Exhibit 12, Testing Records) . Moreover, there is no evidence that testing done on 10/04/2006, 01/21/2008, 12/29/2008 was performed using FDA-licensed, approved or cleared donor screening tests.

Fourth, Mr. Arsenault failed to collect donor specimens to be tested for communicable disease agents at the appropriate times. Specifically, as explained on the FDA-483, he collected a blood specimen seven times, on 10/04/06, 12/18/06, 1/21/2008, 12/29/2008, 05/05/2009, 8/28/2009, and 7/28/2009, and during this timeframe recovered and distributed 328 donations. (Exhibit 2, FDA-483, Observation # 3, page 2).[8] According to the FDA

[8] Mr. Arsenault provided the FDA investigator with a calendar of donations. (Exhibit 2, FDA 483, Observation # 3, page 3; Exhibit 13, Establishment Inspection Report, page 17 of 24).

investigator, only 19 of these 328 donations were collected at the appropriate time. Id. In response to this observation, Mr. Arsenault explained to the investigator during the inspection (Exhibit 13, Establishment Inspection Report, page 17 of 24; and Exhibit 14, STD Policy collected during the inspection), that he understood adequate testing of a directed donor to be once every six months. The investigator explained, and we reiterate here, that such timing would be adequate if Mr. Arsenault was quarantining and storing his recovered semen and then being retested for communicable diseases six months after recovery. 21 CFR 1271.80(b)(2). But because this is not Mr. Arsenault's practice, a six-month time frame is not adequate. He was required to collect a donor specimen for testing at the time of recovery, or up to 7 days before or after recovery. 21 CFR 1271.80(b).

Mr. Arsenault, in his 483 response, does not even attempt to explain away the gaps in testing and his failure to adhere to FDA regulations requiring donor eligibility determinations, instead arguing that he was not required to make donor eligibility determinations because he was the sexually intimate partner of the recipients. (Exhibit 6, page 2). As we have explained repeatedly, there is no evidence that Mr. Arsenault is the sexually intimate partner of his recipients, and the exception afforded sexually intimate partners is not applicable.

Fifth, Mr. Arsenault, as the establishment responsible for donor screening, failed to screen the sole donor, himself, by reviewing the donor's relevant medical records for risk factors for, and clinical evidence of, relevant communicable disease agents and diseases. He also failed to review the donor's relevant medical records for communicable disease risks associated with xenotransplantation. It appears as if Mr. Arsenault made an attempt to screen himself, the sole donor, but he greatly missed the mark.

To more fully explain, Mr. Arsenault was required to screen the donor by reviewing the donor's relevant medical records. 21 CFR 1271.75(a). Relevant medical records include a current donor medical history interview and a current physical examination. 21 CFR 1271.3(s). Mr. Arsenault failed to present any evidence that he obtained a physical examination during the period between December 2006 when he began distributing semen donations and the time of the inspection. On three occasions Mr. Arsenault utilized the "Lifestyle Questionnaire," collected during the inspection and attached (Exhibit 15, Lifestyle Questionnaire) but this screening tool does not comply with the regulations. This questionnaire fails to screen the donor for communicable disease risks associated with xenotransplantation. In other words, Mr. Arsenault has not and cannot raise any issue of fact regarding his failure to properly screen the donor as required by 21 CFR 1271.75.

Sixth, Mr. Arsenault also admitted during the inspection that he failed to determine whether a donor is eligible based on results of required donor screening and testing. 21 CFR 1271.50(a). He simply stated during the inspection, that he never determined the donor to be eligible to donate semen. (Exhibit 2, Observation #1).

Seventh, the Order charges that Mr. Arsenault failed to ensure that the distributed semen was accompanied by a summary of records used to make the donor eligibility determination. 21 CFR 1271.55(a)(3) and (b). During the inspection, Mr. Arsenault admitted that all 328 semen donations were distributed without the required accompanying records. (Exhibit 2, Observation #5). Mr. Arsenault has presented no evidence countering this charge, and in response to the 483 Observation detailing this violation, Mr. Arsenault simply argues he did not need to comply because of his purported status as a sexually intimate partner.

(Exhibit 6, Request for a Hearing, page 2)

Last, the Order charges that Mr. Arsenault fails to comply with record retention requirements in 21 CFR 1271.55, and failed to establish and maintain procedures for all steps performed in testing, screening, and performing donor eligibility, 21 CFR 1271.47(a). FDA investigators noted that Mr. Arsenault has not maintained the required records, (Exhibit 2, Observation #5) and failed to develop written procedures (Exhibit 2, Observation #6). Mr. Arsenault presented no evidence at the conclusion of the inspection, in response to the FDA-483, or since publication of the Order that he had complied with this requirement. His explanation that he need not comply because of his status as a sexual intimate partner is easily dismissed. This explanation raises no genuine or substantial issue of fact to justify a hearing.

CONCLUSION

Mr. Arsenault does not provide adequate protections against the risks of communicable disease transmission prompting FDA to issue an Order to Cease Manufacturing until compliance with Part 1271 has been achieved. 21 CFR 1271.440(a)(3). Although Mr. Arsenault argues that he is entitled to a hearing on whether this Order was properly issued, he has failed to meet basic requirements in FDA regulations regarding determining donor eligibility. His explanation, that he is the sexually intimate partner with those to whom he donates, is nothing more than an attempt to skirt the law and is offered without a shred of evidence. FDA cannot accept an expanded definition of the term 'sexually intimate partner'. To do so, would create a hurdle for the very individuals Mr. Arsenault claims to be helping. It would create a hurdle to the protections offered by the donor eligibility requirements.

Mr. Arsenault has failed to raise any genuine and substantial issue of fact. Because the undisputed facts of record support CBER's Order to Mr. Arsenault to cease manufacturing HCT/Ps, the Commissioner should deny Mr. Arsenault's request for a hearing and enter administrative summary judgment.

Respectfully submitted,

Denise Zavagno
Counsel for the Center for
Biologics Evaluation and Research

Date: February 7, 2011