



Health Products and Food Branch Inspectorate
400-4595 Canada Way
Burnaby, B.C.
V5G-1J9

December 2, 2010

Via e-mail: info@footprint_solutions.com.au
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Dear Ms. Hartnell-Baker,

It has come to the attention of Health Canada that the following websites are facilitating and promoting the availability and distribution of fresh donor semen for assisted conception in Canada:

<http://www.free-sperm-donations.com/>
<http://www.sperm-donors-worldwide.com/>
http://www.sperm-donors-worldwide.com/donors_canada.htm

This practice is in contravention of the Canadian *Food and Drugs Act* and the *Processing and Distribution of Semen for Assisted Conception Regulations* (Semen Regulations).

Under the *Food and Drugs Act* donor semen is considered a drug and as such the distribution, processing and importation of donor semen must be conducted as per all applicable sections of the *Food and Drugs Act* and the Semen Regulations.

Under the Semen Regulations, assisted conception is defined as a reproductive technique performed on a woman for the purpose of conception, using semen from a donor who is not her spouse or sexual partner. As per Section 4(1) of the Semen Regulations no person shall distribute donor semen unless it is processed in accordance with section 9 to 11 of the semen regulations and has been quarantined for a minimum of 6 months and the donor has been assessed against the exclusionary criteria in the referenced Technical Requirements for Therapeutic Donor Insemination. In addition, all testing must be conducted as per the requirements of work-up, repeat screening and quarantine and microbiology both at initial donation and after the 6 month quarantine. Therefore, the use of fresh semen for assisted conception is prohibited under the Semen Regulations.

The Donor Semen Regulations and the associated Technical Requirements for Therapeutic Donor Insemination can be found at:

<http://laws.justice.gc.ca/en/F-27/SOR-96-254/index.html>

http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/semen-sperme-acces/semen-sperme_diactive-eng.php

A review of your websites has indicated that as of November 26, 2010, there were 165 Canadian semen donors available to provide fresh donor semen to Canadian women for assisted conception.



Under section 9(1) of the *Food and Drugs Act*, it is prohibited to sell, offer for sale or advertise a drug in a manner that is likely to create an erroneous impression regarding its character, value, composition, merit or safety. The advertisement of donor semen for assisted conception not processed in accordance with the Semen Regulations is in violation of Section 9 of the *Food and Drugs Act* because it could create an erroneous impression regarding the safety of the donor semen.

Although you may not be directly "selling" donor semen for assisted conception on your website, it is important that you understand your obligation not to assist any person in committing an offence, including an offence under the *Food and Drugs Act*. This would include assisting others (i.e. customers) to obtain donor semen that has not been processed according to the Semen Regulations. Section 21 of the Criminal Code specifies that a person is a party to an offence if they aid another person in committing an offence:

21. Everyone is a party to an offence who

- (a) actually commits it;
- (b) does or omits to do anything for the purpose of aiding any person to commit it; or
- (c) abets any person in committing it.

The continued advertisement and promotion of donor semen for assisted conception that is in violation of legislative requirements is a serious concern that may result in more stringent enforcement action. Therefore, all references to Canadian donors from the above noted websites must be removed immediately.

Written confirmation of your corrective actions is requested by Monday December 6, 2010.

Please note that a copy of this letter is also being sent to the Australian Regulatory Authority and further follow-up will take place.

Further information pertaining to the regulation of health products and the compliance and enforcement activities of the Health Product and Food Branch Inspectorate can be found at:

<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/index-eng.php>

If you have any questions or if you wish to discuss the contents of this letter, please do not hesitate to contact me,

Thank you,

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cc: Regulatory Compliance Unit, Therapeutic Goods Administration, Australia