

USA – FDA

Xytex Involvement

Human reproductive tissues including sperm, oocytes, embryos and gonadal tissue processed for clinical use in patients in American have been subject to 21 CFR (Code of Federal Regulations) Part 1271 since 25 May 2005. A copy of 1271 is [here](#). Xytex Corporation and Xytex Ovations Ltd. registered their processing activities with the FDA in a timely manner and have received identification numbers:

Xytex Corporation: 1000507143 (Augusta)
3003420280 (Atlanta)

Xytex Ovations Ltd.: 3004562441 (Augusta)

Note that XTS (Xytex Tissue Storage Inc.) is not required to be registered. All tissue processing establishments registered with FDA are listed on the Web at two different sites (with different levels of information) www.fda.gov/cber/tissue/hctregtable/htm, www.fda.gov/cber/tissue/hctregtable/htm.

Registered establishments are subject to FDA inspection for compliance with 1271. These establishments must adhere to strict rules governing donor recruitment, donor evaluation and records to be provided to clinics using cells and tissues they have processed. After 25 May 2005 **FDA exempts from registration those clinics using cellular material obtained from a registered manufacturing establishment.** These rules have raised a lot of questions; the response of Xytex to some of these questions can be found [here](#).

It is important to understand that FDA requirements for donor evaluation is limited to testing and/or screening for a specific list of communicable (infectious) diseases. Some states, but **NOT** the FDA, require specific genetic tests. However, the FDA does require that all tests (even those not required by the FDA) used to evaluate a donor be reported to any clinic using his/her cellular materials (1271.3(s) and (x)). Xytex provides a Summary of Records (as required by FDA) including the results of the evaluation procedures related to each tissue specimen; a sample of this Summary of Records for semen is found [here](#).

A Summary of Records for oocytes is found [here](#).