

97N-484R

8/18/04

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

I am attaching comments to the Draft Guidance for Industry Eligibility Determination, Docket No 97N-484R. These were written by our medical director after reviewing the document.

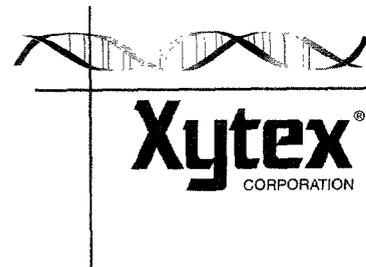
We hope these comments will be considered in determining the final rule.

Sincerely,



Susan Simmons
VP of Clinical Operations

Enclosed comments from J. Todd Spradlin, MD (Medical Director)



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Nucleic Acid Testing

Nucleic acid testing (NAT) is NOT included in the list (Section V.A. 1-5) of recommended tests. However, the comment following this section states “FDA does recommend that living donors of HCT/Ps...be tested with FDA-licensed NAT blood donor screening tests for HIV and HCV.” And in a subsequent paragraph of the same section the following comment appears: “Nonrecommended tests: You or someone else might perform additional testing not listed in section V.A. (for example, NAT).”

These comments seem contradictory and leave it unclear whether or not NAT testing of HIV and HCV is recommended. Semen from anonymous donors is quarantined and negative serologic testing for HIV and HCV after six months is required to release the semen from quarantine. As such, we feel that NAT testing is unnecessary. Clarification is needed regarding NAT testing for HIV and HCV.

Cytomegalovirus

Section V.B. includes the following comment: “CMV is not a relevant communicable disease or disease agent.” A subsequent comment reads “We recommend that... the SOP limit use of an HCT/P based on CMV-reactive status of the recipient.”

These comments seem contradictory and leave unclear the recommendations of the FDA regarding this issue. A large percentage of U.S. adults are seropositive (IgG-positive) for CMV. Similarly, a large percentage of anonymous semen donors are seropositive. Limiting use of an HCT/P based on the CMV status of recipients would severely limit the recipients choices. We feel it is more appropriate to test for CMV IgG and IgM in donors and exclude donors while they are IgM-positive (ie, when the risk of transmission would be likely). Furthermore, we feel that it is the responsibility of the recipient’s physician to discuss CMV status issues and to determine the potential risks of transmission with use of a particular donor.