

Thomas, Terrolyn

From: Thomas, Terrolyn
Sent: Thursday, September 29, 2011 10:05 AM
To: Zdanowski, Michael J; Quinley, Eva
Cc: Karandish, Safa; Rubinstein, Pablo; Scaradavou, Andromachi; Dobrila, Ludy
Subject: INFORMATION REQUEST

Hello:

We received the revised SOP CB41.0002.3 that addresses the issue regarding T.cruzi testing. However, we still need to receive the revised donor eligibility SOP to address the retrospective HIV/HCV NAT testing issue. You have resubmitted the same version of the donor eligibility SOP (CB37.0023.4) in your latest amendment. **Please submit the requested information TODAY if possible.**

Thanks,
Terrolyn

Terrolyn B. Thomas, MS, MBA
Regulatory Project Manager
Office of Cellular, Tissue & Gene Therapies
CBER/FDA
1401 Rockville Pike HFM-705
Rockville, MD 20852-1448
Phone: 301-827-9161
Fax: 301-827-9796
Terrolyn.Thomas@fda.hhs.gov