Thomas, Terrolyn

From: Thomas, Terrolyn
Sent: Friday, September 30, 2011 10:56 AM
To: 'Scaradavou, Andromachi'
Cc: 'Quinley, Eva'; 'Rubinstein, Pablo'; 'Zdanowski, Michael J'; 'Ciubotariu, Rodica'
Subject: RE: INFORMATION REQUEST

Hello,

Please note your approach stated below is acceptable.

Regards,
Terrolyn

Terrolyn B. Thomas, MS, MBA
Regulatory Project Manager
OCTGT/CBER/FDA
Phone: 301-827-9161
Terrolyn.Thomas@fda.hhs.gov

From: Scaradavou, Andromachi [mailto:AScaradavou@NYBloodCenter.org]
Sent: Friday, September 30, 2011 9:42 AM
To: Thomas, Terrolyn
Cc: Quinley, Eva; Rubinstein, Pablo; Zdanowski, Michael J; Ciubotariu, Rodica; Scaradavou, Andromachi
Subject: RE: INFORMATION REQUEST

Dear Safa,

Thank you for yor clarifications. Our concern is that the Donor Eligibility SOP will require extensive changes regading the units with retrospective maternal testing, with the introduction of the term "incomplete" eligibility, etc, but these will need to be finalized after FDA approves our proposal. CB units with retrospective maternal testing will not be licensed, since they do not meet all FDA Licensure criteria. So, the way we have approached this problem for the BLA is through the Release SOP (SOP CB41.0002), since this SOP discusses all aspects of release of a licensed unit. In the version we just submitted, we have introduced the following text (seen in blue), to assure that no unit that does not meet all FDA criteria can be released as a licensed product.

Does this addresss sufficiently your concerns?

Note:

1. Units collected after August 1, 2011, have all CBU records reviewed and approved by Quality and the status of the unit (i.e., whether it is a licensed unit, or will be released under the IND) determined, prior to entering the Search Inventory. As a result, completion of all reviews, including Quality, has taken place before release for transplantation.
2. Units collected prior to August 1, 2011, that meet all other FDA Licensure

criteria, will be reviewed by Quality retrospectively, before they are released for transplantation as licensed units.

Thank you very much for your consideration and looking forward to your response.

Respectfully,

Machi Scaradavou, MD

From: Thomas, Terrolyn [Terrolyn.Thomas@fda.hhs.gov]
Sent: Thursday, September 29, 2011 2:41 PM
To: Scaradavou, Andromachi
Cc: Quinley, Eva
Subject: FW: INFORMATION REQUEST

Dear Dr. Scaradavou:

Thank you for getting back to us so quickly. I realize that you are still working on the proposal and that is fine. However, in order to complete the BLA review, I would need to have the revised donor eligibility SOP that addresses this issue. If your SOP specifies that units tested using frozen samples that don't meet the test kit manufacturers storage limit will not be eligibility for licensure, it would be acceptable for now. You can later complete and submit your proposal for handling such units under your IND.

I hope this is workable for you and the revised SOP can be submitted by tomorrow if at all possible.

Thank you again.

Best regards,

Safa

From: Scaradavou, Andromachi [mailto:AScaradavou@NYBloodCenter.org]
Sent: Thursday, September 29, 2011 10:41 AM
To: Thomas, Terrolyn; Zdanowski, Michael J; Quinley, Eva
Cc: Karandish, Safa; Rubinstein, Pablo; Dobrila, Ludy
Subject: RE: INFORMATION REQUEST

Terrolyn,
We have had discussions with the FDA reviewers regarding donor eligibility and retrospective maternal NAT testing and we are in the process of submitting a proposal to the FDA. Upon approval of our proposal we will make the final changes to the Donor eligibility SOP. Units tested retrospectively for NAT with testing performed not according to manufacturer's specifications will NOT be eligible for Licensure
Thank you
Machi Scaradavou, MD

From: Thomas, Terrolyn [Terrolyn.Thomas@fda.hhs.gov]
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

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