RHODE ISLAND BLOOD CENTER

07/11/2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20857

Re: Docket Number 2003D-0236

Dear Dr. Biswas:

I am writing to comment on the Draft Guidance for Industry, "Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis" published June 2003.

Healthcare Provider Services, Inc., d.b.a. Rhode Island Blood Center (878/12007) implemented the Olympus PK-TP assay system in August 2002. Soon after, we began deferring donors who had positive tests confirmed by FTA who knew of their past history of treated syphilis. Some of the histories are in the remote past and to require the donor to provide documentation of treatment may be onerous or impossible. I think the re-entry algorithm would be more realistic to allow the donor re-entry after the negative non-treponemal test with the information that the donor had been treated in the past, but without the requirement to provide documentation of past treatment.

As required by the state of Rhode Island, we send our donor samples for FTA confirmatory testing to the state laboratory, which is CLIA-qualified but not FDA registered. The requirement of sending a sample to an FDA registered laboratory may necessitate our drawing another tube from the donor and sending it for testing to an FDA registered lab. This in itself will create many problems not the least of which may be the receipt of conflicting results.

In addition, I do not agree with labeling units as reactive by a screening test for syphilis and negative by FTA or other specified confirmatory test. By having a negative confirmatory test, the unit is cleared as acceptable for transfusion, yet this labeling will brand the product as having a defect which, once a consignee sees the labeling, will return to the blood center as unwanted.

Thank you for your consideration of my comments and please feel free to contact me at 401-453-8393 for further discussion of this guidance.

Sincerely,

Carolyn T. Young

Carolyn Te Young, M.D.

2003D-0236

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