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STATE OF NEW YORK
OFFICE OF THE STATE COMPTROLLER

April 3, 2012

Ms. Bonnie B. DeJoy
Corporate Vice-President of Regulatory Affairs
Trinity Biotech
2823 Girts Road
Jamestown, NY 14701

Re: Determination of Appeal of Agency Protest Determination
SAF-1103310113 – Newborn Sickle Cell Disease Testing Reagents and Cartridges

Dear Ms. DeJoy:

This is in reply to your letter of December 22, 2011 appealing the bid protest determination of the Department of Health ("DOH") of December 15, 2011 which upheld the protest of Bio-Rad Laboratories and rescinded the original contract award made to your company on the grounds that Trinity Biotech's bid was not responsive. The DOH subsequently made a contract award to Bio-Rad Laboratories, the second low bidder.

The December 15, 2011 finding made by DOH addressed Bio-Rad Laboratories' assertion that "[t]here is no publicly available information showing that the [Trinity Biotech] Genesys product has been cleared by the Food and Drug Administration (FDA) for newborn screening or for dried blood spot testing, and therefore does not satisfy the bid criteria." The DOH concluded that "the documentation that Trinity provided did not give adequate confirmation of FDA clearance of test kits, which is one of the mandatory criteria within the minimum specifications of the bid." The DOH further noted that "[a]ccording to our interpretation of the FDA guidance document *Deciding When to Submit a 510(k) for a Change to an Existing Device* ... the redesign, change of specimen type, and relabeling of the system suggest that the FDA would expect another 510(k) application for expanded product clearance."

In your appeal to this Office, it appears that you concede that no additional FDA 510(k) approval was obtained for the Primus Genesys Variant System that you proposed to provide to DOH. Rather, it appears that it is your position that the original FDA 510(k) clearance letter of March 1, 1996 obtained for the Primus Variant System PVS99 is sufficient and that any modifications to the approved Primus Variant System PVS99

reflected in the product being offered to DOH do not require an additional FDA 510(k) filing and approval. In this respect, your appeal states that "[a]s the FDA is not in the practice of writing formal letters stating when a product needs an additional FDA 510(k) filing for device modifications, individual manufacturers must document their decision based on their interpretation of the FDA guideline, *Deciding When to Submit a 510(k) for a Change to an Existing Device*." You also provided a copy of a letter from the law firm of Hogan Lovells (which you stated are experts in the field of biotechnology law and patents), who opined that "[b]ased on the regulatory analysis and testing that Trinity Biotech has conducted on the Primus Genesys Variant System, in our view, the company has a valid regulatory and legal argument that the product is legally marketed in the United States."

By letter dated January 20, 2012, this Office notified you that your December 22, 2011 letter was deemed to be a formal Appeal to the Office of the State Comptroller ("OSC") of DOH's December 15, 2011 protest determination. The OSC also requested that DOH submit a supplemental protest determination setting forth in additional detail the basis for rescinding the contract award to Trinity Biotech, and specifically considering the arguments contained in your letter. You were also advised that OSC's Contract Award Protest Procedures allowed your company 10 business days from receipt of DOH's supplemental protest determination to file a supplemental Appeal.

On March 13, this Office received the supplemental protest determination from DOH (which was forwarded to you on March 16). In it, DOH stated that it rescinded the award because it found that your company "failed to provide adequate confirmation of FDA clearance of test kits for our stated purpose, a mandatory criterion within the minimum specifications of the bid." It noted that since the crux of the dispute rests with the interpretation of the FDA guidance document, Wadsworth Center staff contacted the FDA, which advised:

> Based on the information you have provided (Trinity's bid specifications), Trinity Biotech does need a 510(k) for their Hemoglobin variants assay on the Ultra 2 instrument. Additionally, using non-FDA cleared/approved reagents with a cleared/approved assay or instrument constitutes off label use and therefore the assay on the instrument in question would no longer be considered to be FDA-cleared or approved.[1]

On March 20, 2012, this Office received an e-mail from you which stated that while we respectfully disagree with "your" conclusion, "we will honor your decision."[2]

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[1] The FDA response was in an e-mail dated February 15, 2012 from Karen Bijwaard, a Scientific Reviewer with the FDA.

[2] It is noted that the decision apparently referenced in this response was made by DOH, not this Office.

The issue presented by the appeal is whether DOH properly determined that Trinity's bid was non-responsive because it did not submit adequate confirmation of FDA clearance of its product for the purpose stated in the DOH Invitation for Bid ("IFB") as a mandatory criterion within the minimum specifications of the bid.

Since the DOH determination was based on its interpretation of applicable FDA standards, and the response from the FDA appears to affirm that the product being offered by your company to DOH for its stated purpose requires a new FDA 510(k) filing and approval, we have no basis to question the validity of DOH's determination. Accordingly, we are upholding DOH's determination to rescind the original award to your company and are approving the contract with the lowest responsive bidder, Bio-Rad Laboratories.

Sincerely,

Charlotte E. Breeyear
Director, Bureau of Contracts

CEB:arr

cc: Janette Stockert - Bio-Rad Laboratories
Sharon Featherstone - Department of Health