

August 20, 2018

Betsy R. Bombick  
Director, Non-Clinical Studies  
RAI Services Company  
401 N. Main Street  
Winston-Salem, NC 27101

**Re: FDA CTP Request for Information Related to Labstat Project Code M125**


Dear Ms. Bombick

Pursuant to your email dated August 14, 2018, FDA Center for Tobacco Products (CTP) has questions related to a submission which included results from the Labstat project coded M125. You indicated that CTP has requested a copy of TBA-504 as follows: **"provide the complete protocol for "Labstat Method TBA-504" referenced for the in vitro sister chromatid exchange assay"**. You have also noted that the assays were conducted in February/March 2010; the final report (Revision 2) was issued January 13, 2011.

Included with this letter is copy of the method that can be submitted to FDA. The method is as of the date noted above. We ask that you inform FDA that this method is proprietary to Labstat, must remain confidential and may not be made public in any way. Any questions related to any publication must referred to Labstat, attention Mr. Lucian Hirtie, address and main phone number can be found below.

Please feel free to contact me if you have any questions.

Regards



Andrew Mooney  
Vice President, Business Development and Marketing  
Labstat International Inc