RE: PharmaTech, LLC Voluntary Nationwide Recall

Dear Mr. Phillips,

On August 8, 2016, PharmaTech, LLC, Metron’s FDA Registered Contract Manufacturing Organization (CMO) issued a voluntary recall of all liquid nutrition supplements it manufactured from October 20, 2015 through July 15, 2016. The voluntary recall was made as a precautionary measure due to the potential risk of product contamination with *Burkholderia cepacia*.

This recall was instituted with the full knowledge of the U.S. Food and Drug Administration (FDA). PharmaTech’s recall can be viewed at [http://www.fda.gov/Safety/Recalls/ucm515610.htm](http://www.fda.gov/Safety/Recalls/ucm515610.htm).

To date, PharmaTech, LLC has not received any complaints of contamination in the product manufactured for 180 Degree Solutions and known as CytoDetox.

Lot# 30661601 of CytoDetox was manufactured by PharmaTech, LLC between the dates provided above.

This production Lot of CytoDetox was originally tested at the CMO according to FDA/cGMP requirements using USP <61>, USP <62> methods and passed this microbiological test for product safety.

For added assurance and in going beyond FDA’s cGMP standards, Metron also tested CytoDetox Lot# 30661601 at an FDA Registered, Third Party Independent
Laboratory according to the FDA/cGMP/USP <61>, <62>. CytoDetox Lot# 30661601 passed the Third Party microbiological test for product safety.

The FDA microbiological product safety test according to cGMP/USP <61>, USP <62> applied by Metron and its CMO does not require testing for *Burkholderia cepacia*.

However, following PharmaTech's voluntary recall, Metron had an additional test performed on CytoDetox Lot# 30661601 for *Burkholderia cepacia* at an FDA Registered, Third Party Independent Laboratory. The CytoDetox Lot# 30661601 test result is negative for the presence of *Burkholderia cepacia*.

As an additional QA/QC measure, starting September 2016, Metron will keep testing CytoDetox, Lot# 30661601 monthly until the Expiration Date of the product (May 2018) and will provide you monthly updates on the test results.

Based on the additional monthly testing commitment, the negative results of both the extra microbial testing, and the organism specific testing, Metron feels that the product is safe for its intended purpose.

Metron has always strived for and will continue to insist on honesty, complete transparency and ethical safety standards that go well beyond those applied in the nutraceutical industry.

Sincerely,

*Nikolaos Tsirikos-Karapanos*  
PharmD, MD, PhD, FETCS  
President  
Metron Nutraceuticals, LLC