

February 19, 2013

Ms. Leslie Kux  
Assistant Commissioner for Policy  
Food and Drug Administration  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket No. FDA-2013-N-0333

Dear Ms. Kux:

Microbiologics, Inc. appreciates this opportunity to comment on the proposed recordkeeping requirements for microbiological testing and corrective measures for bottled water. Microbiologics, located in St. Cloud, Minnesota, produces a uniquely qualified array of the most highly accredited biological reference materials used in food, clinical, pharmaceutical, cosmetic, water and environmental laboratories.

We agree with the Food and Drug Administration's statement that "source water found to contain *E. coli* is not considered water of a safe, sanitary quality and would be unsuitable for bottle water production." We find the requirement reasonable for sources, previously found to contain *E. coli*, to be considered negative for the pathogen after five samples collected over a 24-hour period from the same sampling site are tested and found negative for *E. coli*.

While we encourage this measure, we do note that there is no mention of quality laboratory testing practices. If quality assurance practices are not followed, repeating a test from the same sampling site over a specific time period may not accurately verify the test. In other words, if a test is not performed correctly, it may not matter how many times it is performed.

It may be helpful to note that the Environmental Protection Agency issued a final rule on revisions to the total coliform rule on February 13, 2013. It states that *E. coli* is a more specific indicator of fecal contamination and the potential presence of associated pathogen occurrence than fecal coliforms. This rule establishes a maximum containment level goal and maximum contaminant level for *E. coli*. The maximum contamination level goal for this pathogen is set at zero.

If you have questions or need additional information, please let me know or contact Robin Stombler at 202-390-3932.

Sincerely,



Brad Goskowicz  
Chief Executive Officer