

May 20, 2013

VIA EMAIL AND FIRST CLASS MAIL

Keith Moeller
American Biotech Labs
80 West Canyon Crest Road
Alpine, Utah 84004

Re: Safety of ABL's Dietary Supplements

Dear Mr. Moeller:

You have asked us whether American Biotech Labs (ABL)'s Silver Biotics products can be represented in labeling and advertising as safe. We understand that you have determined that ABL's Silver Biotics products are lawfully marketed as dietary supplements. As detailed below, all products lawfully marketed as dietary supplements must be safe, and therefore once a product has been determined to be lawful, it may be represented as safe. In addition, we have evaluated the studies you have provided, which further support the safety of your products.

To be lawfully marketed as a dietary supplement, a product must be safe under its recommended, suggested, or normal conditions of use. Under section 402(f) of the Federal Food, Drug, and Cosmetic Act a product is deemed adulterated if it is unsafe because it presents a significant or unreasonable risk of illness. FD&C Act § 402(f), codified at 21 U.S.C. § 342(f). Since ABL's products have not been deemed adulterated, they are considered safe under the FD&C Act. FDA also has additional requirements to ensure that all ingredients used in dietary supplements are safe. Any dietary supplement compliant with the requirements of the FD&C Act is safe and can be called safe. No IRB clinical trial is needed for a dietary supplement to be called safe.

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We have also evaluated the studies you have provided, and we find that they provide a reasonable basis for concluding the product is safe. We analyzed the report prepared for FDA by Mark A. Munger, Professor at the University of Utah, along with the accompanying article, “*In Vivo* Human Time-Exposure Study of an Orally-Dosed Commercial Silver Nano-Formulation.” Professor Munger studied exposures to American Biotech Laboratory’s 10-ppm and 32-ppm silver solutions for fourteen days. The clinical measurements, the number of participants (sixty healthy volunteers age 18-80), and the design of the study—double-blind, placebo-controlled, cross-over—are appropriate for evaluating safety. With both the 10-ppm and 32-ppm silver solution, the studies found no observable clinically important toxicity markers.

In addition to the human clinical trials with oral doses discussed above, we reviewed two other toxicity studies using American Biotech Laboratory’s silver solutions: (1) an injection study in animal model; and (2) an *in vitro* study using human and monkey cell lines. From the information you provided to us, we understand that the results of the injection study, conducted by the Shri C. B. Patel Research Centre, show that injection of ASAP 10-ppm silver solutions produced no abnormalities in an animal model. These results are consistent with a pilot toxicity study, conducted by Dr. Hegde of Kasturba Medical College, involving silver nanosolutions given orally to rats for 28 days, which found that escalating doses of silver nanosolution were safe in rats. The *in vitro* study by Viridis BioPharma assessed the cytotoxicity of ASAP at 10 and 22 ppm silver in primate and human cell lines. Neither the 10 or the 22 ppm solution showed any negative effects relative to control, indicating no cytotoxicity.

Finally, an *in vitro* study by Viridis BioPharma shows no effect of ASAP at 10 and 22 ppm on lactic acid bacteria—probiotics that inhabit the human gut and aid in digestion. Although not a toxicity study like those considered above, it supports the conclusion that ABL’s silver-based products do not produce adverse health effects.

COVINGTON

COVINGTON & BURLING LLP

Keith Moeller

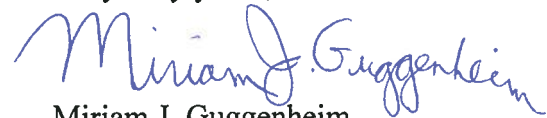
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In sum, since your products are lawfully marketed as dietary supplements under the FD&C Act, they can be represented as safe for their conditions of use. The safety of your products are further supported by the human clinical studies and toxicity studies discussed above.

Please let us know if you have any further questions.

Very truly yours,



Miriam J. Guggenheim

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