

April 27, 2015

Statement on use of DNA testing for identification of Aloe vera

[Note: This statement provides the view of the International Aloe Science Council (IASC) of the current state of the science of the use of DNA barcoding as a technique for authenticating the identity of aloe vera and is intended to explain the currently limited applicability of this analytical technique to the identity testing of aloe vera and other botanical materials.]

Similar to the botanical products scrutinized by the New York Attorney General’s investigation into several popular dietary supplement products, aloe vera is a botanical for which DNA-barcode testing has not yet become a routine analytical method for the identity testing required for dietary supplement ingredients under 21 CFR 111. For the raw, unprocessed aloe vera juice, it is highly likely that DNA is detectable. Once the aloe vera raw material is processed by extraction, heating/pasteurization, filtration, etc., any DNA is likely to become denatured or destroyed, such that it would be non-detectable in a finished product. As noted by Dr. Gabriel Giancaspro of United States Pharmacopoeial Convention (USP), “bar coding is not particularly useful for highly processed materials. For botanicals, we know that the solvents and the process to extract and purify the desirable compounds can exclude DNA.”

The predominant analytical test for aloe vera ingredients is analysis for acemannan, a polysaccharide compound, via a validated nuclear magnetic resonance (NMR) testing method. A statement from the FDA Center for Food Safety and Applied Nutrition (CFSAN) confirmed “FDA does not currently use DNA sequencing for dietary supplement ingredient verification. The agency currently uses chemical markers or fingerprints when it performs ingredient verification.” FDA routinely accepts the NMR acemannan analysis as the basis for aloe vera identify testing during their inspections of aloe vera product manufacturers. Additional information on identification and analysis of aloe vera is presented in the American Herbal Pharmacopoeia’s Aloe Vera Leaf monograph (2012).

The IASC administers a third-party certification program designed to verify the purity and quality of products produced from aloe vera. This program includes evaluation of dietary supplement products as well as others such as personal care products and conventional beverages. The IASC program consists of several key components:

- Inspection of the manufacturing facility against good manufacturing practices (GMPs),
- Testing of the aloe vera raw material or finished product for acemannan, a marker compound for the identification of aloe vera,
- Testing for other aloe vera quality parameters per the IASC aloe vera quality standard,



- Review of label information for compliance with applicable regulatory requirements.

Compliant products are allowed to use the IASC certification seal on product labeling and marketing materials. Consumers can have confidence that a product bearing the IASC seal contains the high quality aloe vera they value in their dietary supplement products.

The IASC also endorses the American Herbal Products Association's April 14, 2015 statement on the use of DNA testing for botanical identity, which is available [here](#).