The Impact of the Food Safety Modernization Act

The New Reality

Today's dietary supplement and foods Industries are dramatically changing and "business as usual" is not acceptable in the reformed regulatory enforcement environment. The industry is facing numerous ingredient and product testing challenges that are all high-dollar, high-impact and demand mitigation:

- API spiking
- Managing costly and obscure phytochemical standards
- NDI compliance – the new interpretation and requirements
- Botanical identity methods for pre-mixed blends

Has your organization been impacted by these new regulatory changes? Are you foreseeing significant changes in the near future in the way raw materials and final products are tested?

The FDA's Expanded Role

The FDA is now empowered by FSMA and takes a strong position on quality testing. Violations of the cGMP's under 21CFR part 111 are common and citing ignorance for the law or that no reasonable methods exist are no excuse for noncompliance. Did you know, the FDA now:

- Has direct recall authority or may use US Marshalls to seize products or close facilities
- Can retain imported ingredients, seize products, and freeze assets
- Has raided facilities for FTC marketing violations without prior warning or court action
- Has ramped up inspections, as well as issued warning letters with very limited response time
- Considers ingredients containing undeclared components, including API's, adulterated

FDA warning letters have commonly cited testing issues including:

- Standards not adequately characterized and utilized
- Finished product testing, identity testing, sampling and QC inadequate
- Vendor C of A not validated or requalified

How do you ensure that your incoming raw materials and your outgoing products are free from adulterants? What specific challenges does your laboratory face in meeting these compliance concerns?

Practical Solutions

These changes may seem overwhelming and daunting, but rest assured, there are technologies and expertise available that can be implemented to help address these compliance needs. Flora Research Laboratories (FRL), a leading contract testing laboratory specializing in the research and analysis of botanicals, dietary supplements and related compounds has pioneered the field of "Phytoforensic Science".

Attendees of a recent **USP Workshop on Intentional and Unintentional Adulteration of Food Ingredients and Dietary Supplements** reached consensus regarding testing recommendations for botanicals. Following the presentation by J.N. Kababick of FRL entitled *Erectile Dysfunction and Weight Loss Adulteration: The Contract Lab Perspective*, the group recognized that Flash chromatography should be used to detect analogs. No significant peaks should be ignored.

For additional USP workshop dietary supplement testing recommendations, inquire at conferences@usp.org or visit http://www.usp.org/meetings/workshops/pastUSPWorkshops.html or see "FDA Warning Letters-A Year in Review (2011)" by FRL published 12/29/2011.

The “One-Pass-Flash” Solution for Sample Prep

A new sample prep and isolation technique has been developed at Flora Research Laboratories that addresses the most critical quality-compliance concerns to:

- Uncover and concentrate potentially harmful additives in food and supplements
- Detect and isolate contaminants in botanicals
- Rapidly isolate and purify phytochemical standards for novel botanical products
- Eliminate mass spec matrix interference problems with rapid-flash sample prep

What testing methods are employed and are they adequate?

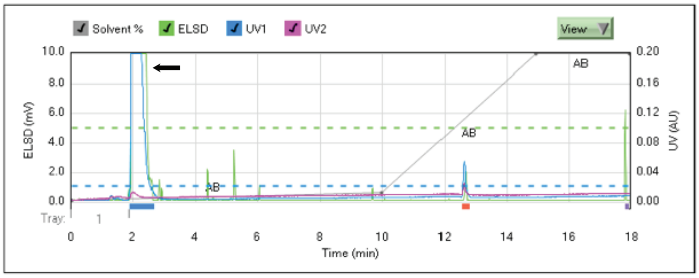
This simple “One-Pass-Flash” method is an advanced separation technique incorporating RevealX™ detection and fully integrated UV/ELSD in flash chromatography. There are many practical applications for this fast, automated and cost-effective chromatographic technique.

U.S. Patents Nos.
8,115,930
8,305,581
8,305,582
8,314,917

For more information about the “One-Pass-Flash” technique and to view presentations by Flora Research Labs, please visit the following sites: www.floraresearch.com or http://www.cosmoscience.org/archive_2011.htm.

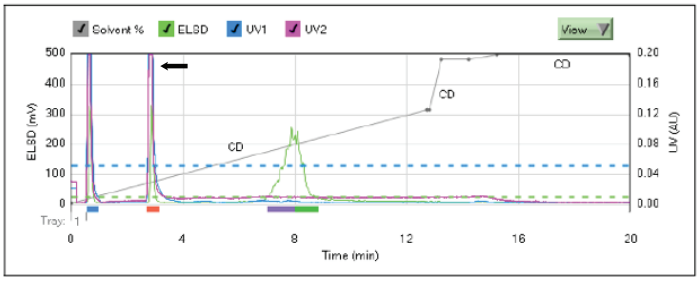
Body-building Supplement Testing

Anabolic androgenic steroids isolated in 2 minutes from a highly complex tribulus mixture in a single fraction pure enough to be directly analyzed by GCMS without further clean-up.



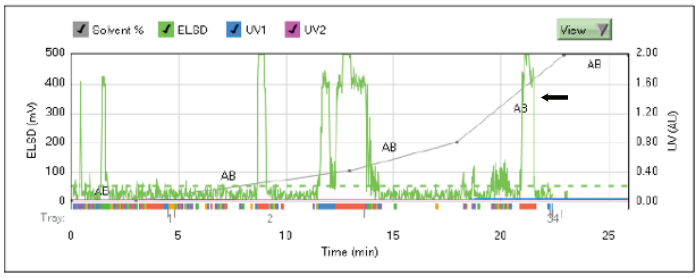
Male Virility Supplement Testing

PDE-5 inhibitor analogues are isolated in about 3 minutes using flash chromatography, yielding enough pure material in one run for LCMS, NMR and FTIR analysis.



Complex Botanical Identity Testing

Schizandra spp extract was fractionated with RevealX™ detection in flash chromatography, yielding nearly pure compounds that are independently detected and collected for use as secondary reference standards.



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