Validated Analytical Methods:

http://www.naturalproductsinsider.com/
By: AOAC International
Posted on: 01/06/2005

PRINT

[Laboratory Insights]

Validated Analytical Methods: The Case for Quality Measurements

by AOAC International

The ability to address many questions relating to the safety and efficacy of dietary supplements is critically dependent upon the existence of high-quality, reliable, validated analytical methods. Similarly, any attempt to level the economic playing field between the majority of reputable manufacturers and the few "fly by night" producers of inferior or mislabeled products will also depend on valid and defensible measurement techniques. These needs run the gamut from measurements of identity, dosage and impurities to the *in vitro* or *in vivo* analyses required in clinical trials. *The Official Methods of Analysis*SM endorsed by AOAC International are unique due to the stringent validation requirements and collaborative studies required for an analytical procedure to gain the status of an AOAC Official MethodSM. These high AOAC standards have earned AOAC methods official recognition by regulatory agencies throughout the world and are specifically cited in the U.S. Code of Federal Regulations.

The current Good Manufacturing Practices (cGMP) are a result of U.S. agencies' efforts to regulate the safety, efficacy and advertising claims made concerning pharmaceutical dosage forms throughout the supply chain. The Good Laboratory Practices (GLP) were the result of falsified animal safety data submitted to regulators upon which decisions were made concerning the safety of pharmaceuticals, pesticides and industrial chemicals. The Good Clinical Practices (GCP) were an agency response to questionable safety data coming from clinical studies, upon which decisions are made as to broad safety and marketability of a product.

Dietary supplements have recently been the focus of attention from regulatory agencies and the general public in large part due to problems encountered with ephedra.These problems gained the attention of national media and generated large amounts of publicity. Is it any wonder, then, that the dietary supplements industry has come under a regulatory microscope? Label claims are certainly a predominant issue. The availability of certified reference materials and validated analytical methods and the consistent application of scientific evidence are needs that, while being addressed, require support so that a leveling of the playing field can be accomplished with minimal disruption to profitability.The overriding need of the regulatory community at this time is reliable consistent methods that accurately and precisely measure content and uniformity.

The U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH), Office of Dietary Supplements (ODS), in 2003 co-sponsored the development of these methods through a contract with AOAC International. Although generous, the contract is limited when one considers the complexities and

magnitude of expert volunteer assistance required to accomplish this monumental task.Why should the dietary supplements industry actively participate in this process?

- **Quality Improvement:** Quality monitoring with validated analytical methods will result in less down time, less rework and fewer recalls. Organizations that actively monitor quality find that quality improves as a result of the monitoring.
- **Supply Chain Improvement:** Are your suppliers reliable? Are new supply sources adequate? Are your low-cost suppliers providing minimum quality materials?
- **Regulatory Success:** Efficient compliance with cGMP, ISO 9000, etc. will result in less regulatory scrutiny and better reputation.
- **Market Control:** Knowledge that the playing field is level as well as developing data to support that products are up to competitive and regulatory standards.
- **Publicity Control:** When problems arise, the availability of validated test methodology allows companies to evaluate potentially damaging information quickly and thus facilitate problem resolution. Product claims can be validated, and damage to brands and goodwill can be avoided from bad publicity.
- **Liability Control:** Use of reliable test methodology helps avoid regulatory problems such as cGMP violations, shutdowns and recalls. They can provide indispensable help in defending against civil claims of unfair competition or lack of due diligence. They can even sometimes avoid criminal problems, where failure to use valid analyses can be construed as willful and knowing misconduct.
- **Goodwill/Intangibles:** Participation on technical committees provides a networking opportunity for new technical and marketing personnel, and develops a company's reputation as a result of such participation. It also assures that companies are kept current with the analytical methods necessary to control their products.
- **Research and Development:** Development and use of validated methodology in the research and development process provides confidence that a product's label claims are achieved by avoiding analytical pitfalls.
- **Laboratory Efficiency:** Sharing the efforts and resources necessary to develop collaboratively tested methods that have the ruggedness to avoid test failures and re-analyses commonly associated with unvalidated procedures results in significant overall cost savings.Validated test methods allow for suitability assessment of the procedure for specific analytical needs.
- **Clinical Studies:** Assurance that products used for clinical studies are properly characterized and meet accepted standards. Reliable analytical methods produce accurate data, which in turn permit valid clinical conclusions to be drawn.

Although not specifically stated in the above list, the cost is considerable in time, resources and money. However, the alternative of each individual business substantiating the validity of its methods and reference standards to an agency investigator would far exceed an earlier, joint investment.

Broad industry representation and participation in this process would benefit all parties, ultimately providing official AOAC defensible methods that are validated to the fitness for use criteria of providing the safety and assurance of dietary supplements offered to the public. It can be rewarding and cost-efficient to work together as partners toward resolution of industry and regulatory issues in a collaborative and scientifically sound manner.

AOAC therefore urges companies to support this joint FDA/NIH venture to provide the dietary supplement industry with legitimate analytical methods for commerce. Consider volunteering some of the time and laboratory resources of a company analytical chemist to share expertise in this endeavor.

AOAC acknowledges the authors that contributed to this article: James Ault, Ricerca; Edward Waysek, Caravan Products; Rick Myers, Weider Nutritionals; James Roza, NOW® Foods; Dana Krueger, Krueger Foods; James Neal-Kababick, Flora Research Laboratories; and Aniko Solyom, University of Arizona. For more information or to get involved, contact James Roza, chairman of the AOAC Task Group on Dietary Supplements, (630) 545-9098, ext. 120, jroza@nowfoods.com; or Anita Mishra, AOAC's principal scientific liaison, government and industry, (301) 924-7077, ext. 131, amishra@aoac.org.