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## Dietary Supplements—an FDA Ruling

The dietary supplement industry has long been faced with issues of efficacy, potency and quality. Until recently, ethical manufacturers self-regulated those issues while others turned a blind eye. In late June the FDA announced a final rule

### The new dietary supplement cGMPs require, in part:

- > Written procedures relating to equipment, manufacturing operations, quality control, laboratory testing, packaging and labeling, and product complaints;
- > Certificates of analysis or testing of incoming components;
- > Batch testing of all finished batches or a subset of finished batches;
- > Preparation and use of a master manufacturing record for each unique formulation and batch size;
- > Preservation of reserve samples of finished dietary supplement batches;
- > Investigation of product complaints that involve a possible failure of cGMP requirements; and
- > Maintenance of records associated with the manufacture, packaging, labeling, or holding of a dietary supplement

For a complete list of requirements visit <http://www.fda.gov/insight/articles/jmoore2007a.pdf>

Companies with less than 500 employees have until June of 2009 while companies with less than twenty employees have until June of 2010.

establishing regulations to require current good manufacturing practices (cGMP) for dietary supplement manufacturing. Consumers can expect that products will not contain contaminants and will be accurately labeled. In addition, manufacturers will be required to report all serious adverse events to the FDA by the close of 2007. This ruling requires manufacturers to identify the products identity, purity, strength and composition. FDA's final rule aims to prevent inclusion of the wrong ingredients, too much or too little of a dietary ingredient, contamination by natural toxins, bacteria, pesticides, glass, lead and other heavy metals as well as improper packaging and labeling.

Companies with more than 500 employees have until June of 2008 to comply.

## Analyses of the Month

### Metals Analysis

For the month of January, DataChem's Salt Lake lab is offering a discount on our metals analysis by NIOSH 7300; a panel of 27 elements for \$100, a single element for \$40 with each additional element for \$15. For further details contact us at [info@datachem.com](mailto:info@datachem.com).

To take advantage of the offer simply refer to the newsletter in your analytical request. Discount is only available at our Salt Lake facility.

### Pesticides

For the month of January, DataChem's Salt Lake lab is offering **Pesticide Analysis for 25% off of our normal rate**. For further details contact us at [info@datachem.com](mailto:info@datachem.com). For a complete list of our Salt Lake lab services visit us at [www.datachem.com](http://www.datachem.com)

To take advantage of the offer simply refer to the newsletter in your analytical request. Discount is only available at our Salt Lake facility.



Some manufacturers take precautionary measures to ensure quality while others do not.

## Dietary Supplement Regulations and the Physician

Herbal remedies have existed for tens of thousands of years, perhaps even longer. Using plants to treat a variety of ailments has often progressed to conventional medicine; up to 25% of modern medicines are based on plant origins. An herbal remedy is a small sub-portion of the dietary supplement industry.

Western medicine has begun to embrace the use of herbs and supplements as concurrent therapy with conventional medicine but how much do physicians know about how supplements are regulated in the United States? A recent survey of 335 physicians discovered that nearly one third of those surveyed were unaware that supplements did not require Food and Drug Administration (FDA) approval or submission of safety and efficacy data prior to going to market. A similar number of physicians believed there were regulations in place to ensure supplement quality. Many were unaware that serious adverse events should be reported to the FDA MedWatch system.

The above excerpt was taken from *Nutraceuticals World*. For the full article visit <http://www.lohas.com/articles/100702.html>

### What you should know about Herbal Remedies

Natural does not equal safe. Information on an herbs potential interaction with prescription medications is often not available.

Remedies may contain more than just herbs to make them appear more effective.

There are often thousands of chemicals in herbs amounting to active ingredients that are unknown and untested.

Due to the amount of uncertainty herbal remedies should never be taken while pregnant or breastfeeding.

Herbal remedies have existed for tens of thousands of years. They have a long track record of use.

Recently, an adverse event reporting system has been implemented.

Herbs and supplements are allowed to be sold to the public without the FDA approval and pre-market evaluation.

**DataChem offers a wide range of Dietary Supplement Analysis. Contact our Project Managers at 1-800-356-9135 for a full list of capabilities.**