



ALS Salt Lake News

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The Food and Drug Administration and Dietary Supplements

The Food and Drug Administration (FDA) is responsible for protecting health by ensuring the safety, efficacy and security of drugs, biological products, medical devices, our nation's food supply, cosmetics and products that emit radiation. In October of 1994 the Dietary Supplement Health and Education Act (DSHEA) was signed into law. The FDA defines dietary supplements as a product taken by mouth that contains a dietary ingredient such as vitamins, minerals, amino acids, herbs and botanicals as well as other substances that can be used to supplement the diet. Prior to this Act, supplements were regulated in the same manner as foods. This new law changed the way in which supplements were regulated by the FDA. Supplements no longer required approval

Current Good Manufacturing Practices (CGMPs)

The FDA is authorized to issue CGMP regulations describing conditions under which supplements must be prepared, packed and stored. The final rule for CGMPs was established in June 2007. It establishes the minimum CGMPs necessary to ensure the quality of the supplement. The FDA states that in order to ensure the quality of a supplement the manufacturer must identify precisely what it will produce, how it will produce the product and which process controls and tests will be used to ensure reliable, reproducible results. Under the final CGMP rule, testing or examinations are used to confirm incoming components and in-process materials meet specifications. Testing and examination is required to ensure that the final product meets specifications and was not unintentionally contaminated or adulterated during manufacturing.

able to take action against a supplement that presents a significant or unreasonable risk of illness or injury or that otherwise adulterated or misbranded. As resources permit, the FDA also reviews product labels and other product information.

from the FDA prior to market. The manufacturer became responsible for determining the safety of its product. The exception to FDA approval prior to market is when a new dietary ingredient is introduced. A new dietary ingredient is defined as a dietary ingredient that was not sold in the U.S. in a dietary supplement prior to October 15, 1994, when DSHEA went into affect. Federal law requires supplements to be labeled accordingly. Federal law does not require supplements to be proven safe to FDA's satisfaction nor does it require a manufacturers claim be proven accurate or truthful; however manufacturers can not market unsafe or ineffective products. The FDA's role with a dietary supplement essential begins after the product is marketed. Once marketed, the FDA has safety monitoring responsibilities. Manufacturers must report any serious adverse events reported to them to the FDA. The FDA is



A supplements quality is strongly dependent on the steps a manufacturer takes to ensure product safety and efficacy.

Source Contamination in Dietary Supplements

Many supplement manufacturers do not make the constituent ingredients of the supplement, but instead purchase these substances in bulk and mix them into a desired formulation. While there are many manufacturers who maintain a high standard of quality control and testing of supplement ingredients, there are also a large percentage of manufactures who do not maintain such standards. Dietary supplement contamination can include heavy metals, pesticides, bacteria, fungi, volatiles and other undesirable adulterants. A source product can be jeopardized by a number of factors in the harvesting, collecting and shipping processes. Product contamination and/or adulteration can also occur during the manufacturing process. Current Good Manufacturing Practices (CGMPs) help to prevent undesirable effects on a product such as superpotent, subpotent, wrong ingredient, contamination, and foreign material within the final product.

ALS Salt Lake can screen for pesticides, organic contaminants (semi-volatiles), residual solvents (volatiles) and heavy metal contamination in supplements. For further information on our screening capabilities call 1-800-356-9135.

Analysis of the Month

Metals

For the month of May ALS Salt Lake 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 For a complete list of Salt Lake's analytical services visit us at 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.

FDA Links on Dietary Supplements

To read the FDA's final rule on CGMPs visit <http://www.fda.gov/ohrms/dockets/98fr/cf0441.pdf>

For general information visit <http://www.cfsan.fda.gov/~dms/ds-oview.html>

For claims that can be made for supplements visit <http://www.foodsafety.gov/~dms/hclaims.html>

Pocket Field Reference Guide Update

The Pocket Field Reference Guide is published and is currently being mailed. If you have requested a guide and not yet received your copy you should see it in the mail next week. For an online copy visit <http://www.datachem.com/2009PocketGuide.pdf>

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