New FDA Regulations for Dietary Supplements

For years, dietary supplements have been scrutinized by the media for being marketed as “snake-oil” cure-alls, potentially containing components considered harmful to consumers. Under-regulation by the Food and Drug Administration (FDA) lead to concerns that these products did not fall under the same regulatory requirements as pharmaceuticals. Until now.

New FDA regulations for the dietary supplement industry aim to eradicate consumer concern and health risks associated with these products. Dietary supplement manufacturers and distributors are now required to follow Good Manufacturing Practices (GMPs) similar to those of the pharmaceutical industry. The FDA 21 Code of Federal Regulations (CFR) Part 111 was established to insure the identity, purity, quality, strength, and composition of dietary supplements and applies to those involved in the manufacture, packaging, labeling or holding of a dietary supplement, with the exception of retail establishments selling directly to consumers.

The federal government is taking a tiered approach to enforcement: companies with more than 500 employees were required to become compliant by June 2008; companies with 21-499 employees must become compliant before June 2009; and companies with fewer than 20 employees will need to be compliant by 2010.

To become compliant with the GMP guidelines, passed in 2007, dietary supplement companies need to perform analytical testing of their products. Analytical laboratory analysis falls under the category of “manufacture” as defined by FDA CFR. Therefore, if testing is not performed the dietary supplement company will be considered non-compliant regardless of the reason for not testing. Reasons for not testing range from it being cost prohibitive to it’s impossible as an option for raw materials, in-process or final products. Those non-compliant and unable to meet GMP guidelines will run the risk of not being able to sell their products due to regulatory agency action. This may result in some companies going out of business or, at the least, an increased need for analytical testing.

In some ways, GMPs for dietary supplements have been considered to be more strict than those for pharmaceuticals. For example, many pharmaceutical compounds can be considered “pure” if they meet 90-98 percent of the requirement. Purity constraints for dietary supplements can be as much or more than 100 percent as a requirement. The GMPs for dietary supplements are a combination of GMPs for both food and drugs. The abundance of new regulations may be a response to the public scrutiny the dietary supplement industries have received in recent years.

GMP compliant analytical testing for GMP guidelines may include residual solvent and heavy metals analysis, water determination by Karl Fischer, and microbial limit testing. These tests are designed to ensure product quality and consumer safety, but there is a need for identity testing and potency as well. Identity and potency will confirm for manufacturers that the product label accurately reflects the actual ingredients as well as potency of each batch or lot of product. In other words, “it is what it is” and the manufacturer has the compliant analytical quality control laboratory documentation to prove it.

This new challenge for production will require substantial new testing in order to maintain compliance. Some dietary supplement companies have already found that outsourcing the testing, though thousands of dollars per year, is a more sensible business strategy than investing millions developing and maintaining their own compliant laboratories. When outsourcing analytical testing to laboratories, the FDA requires the outside lab to be cGMP compliant and FDA inspected. The Quality Unit of compliant laboratories will be able to readily supply information including documentation of quality systems and FDA inspection reports.

Manufacturers may want to assess the most cost effective and efficient means to deal with these new FDA regulations.