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LABORATORY SERVICES

cGMP Regulations for Dietary Supplements Become Law

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The current Good Manufacturing Practice (cGMP) regulations for dietary supplements were implemented in 2008. The FDA defines these regulations as "the minimum current requirements for methods used in, the facilities or controls used for, the manufacture, processing, packing, or holding of a dietary supplement to assure its safety, identity, strength, quality, and purity."

Companies with more than 500 employees were required to comply by June of 2008. Companies with fewer than 500 employees had until June of 2009 and companies with fewer than 20 employees have until June of 2010 to comply with the regulations.

The implementation of these regulations has been a long process, beginning with the Dietary Supplement Health and Education Act of 1994 (DSHEA). The FDA issued an advanced notice of proposed rule making in 1997, followed by a proposed rule in 2003. The final rule was announced in June of 2007 and became effective August 24, 2007. According to the FDA, the goal of the regulations is to "ensure the quality of dietary supplements so that consumers can be confident the products they purchase contain what is on the label." The regulations also include manufacturing controls to preclude unsafe levels of contaminants such as pesticides, bacteria, lead and other heavy metals. The regulations do not address efficacy, only manufacturing.

Although the requirements are not as rigorous as the pharmaceutical GMPs, much of the wording is similar. Manufacturers are required to keep detailed records documenting all standard operating procedures (SOPs) and they must have a formal process for review and updating SOPs. In addition, training records for all employees must be kept current and a master manufacturing record for all formulas must be maintained. The regulation requires extensive record keeping and requires access to these records by the FDA.

Identity testing must be performed on every dietary ingredient used in each batch. This can be performed by the manufacturer or by the supplier, but the manufacturer is responsible for verifying the reliability of the supplier. The ingredient suppliers are exempted from the regulation. The materials must also be tested for possible contamination for such parameters as lead and other heavy metals, bacteria, glass, and pesticides.

The raw material suppliers were not included in the rule because the FDA is putting the responsibility on the manufacturer. However, as a way to deflect some of the costs from themselves, the manufacturers will probably require some of their suppliers to meet these regulations. Also, the raw dietary ingredient suppliers are still subject to the Food GMP regulations.

Finished product testing must also be performed to verify the accuracy of the label claim. The manufacturer must test every batch to comply, but the rule does allow for reduced testing on some batches. Not every component must be tested in every batch as long as the manufacturer has a statistically valid sampling plan to determine the testing frequency. Specifications must be set for each product and there must be verification that the product passes the specification prior to release.

The regulation also contains requirements for controls at the manufacturing plant. These include specifications for the grounds, the plant, and the employees. Some of the items addressed include: staffing levels, quality assurance (QA) and quality control (QC), maintenance of the grounds, plant sanitation, pest control, water supply, packaging, labeling, and plant design. The regulation also includes a discussion of manufacturing equipment, analytical instrumentation, and the duties of quality control personnel.

There are also requirements for the analytical testing methods in the regulation. The requirement is to identify and use an appropriate scientifically valid method for each established specification. Although the FDA does not define the term, "scientifically valid method," some of the examples they provide appear to fall short of the requirements of a fully validated method as defined by USP or AOAC. In recent discussions with the industry, the FDA stated at a minimum, the methods should be verified for accuracy, reproducibility and specificity.

There are no shelf life requirements in the rule; but the rule states that if manufacturers use an expiration date on a product, the date must be backed up by scientific data. Because most retailers insist on expiration dating, this will probably turn stability testing into an unwritten requirement..

Microbac Laboratories, Inc. has been involved in the testing of Nutritional Supplements for over 17 years. During the development of the general chapter for dietary supplements in the 1990s, the USP requested methods from Microbac for the determination of oil-soluble and water-soluble vitamins in multivitamin and multimineral products. These methods were included in the USP as options for the determinations. Our methods have gained respect throughout the industry for their ruggedness and the breadth of products for which they can be used.

Microbac Laboratories, Inc. also has years of experience with the determination of botanical ingredients, both as raw materials (dietary ingredients), and as components in a nutritional supplement. We currently have over 60 analytical methods for botanicals.

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Many of the Nutritional Supplement trade organizations have been involved in helping to shape these regulations for many years, and they can offer members advice on understanding the regulations and compliance.

For more information, please contact: microbac_info@microbac.com