

All Products are not made the same. There are professional products that follow the GMP guidelines and then there are retail supplements that are not required to be tested at all! If you're going to spend money on a supplement, make sure you're getting what you're paying for by purchasing products that have verified what's on the label is in the bottle. That's why I only order from



## (Good Manufacturing Practices)

In June 2007, the FDA published the final GMP regulation specific to dietary supplements. In order to keep the NPA GMP Certification Program relevant and reflect the highest level of industry good manufacturing practices, the NPA GMP Standard has been revised to include all of the FDA GMP requirements of 21 standards and retains certain requirements from the 2000 version of the NPA GMP Standard that exceed requirements of the FDA GMPs, or reflect best industry practices, and/or are necessary for the evaluation of compliance to the NPA GMP standard. ***NPA GMP Certification is awarded to companies that meet a high level of compliance to the NPA GMP Standard as verified through comprehensive third-party inspections of facilities and GMP-related documentation.***

### **CGMP (Current GMP) Final Rule: (2007)**

- The U.S. Food and Drug Administration issued the final rule establishing regulations to require current good manufacturing practices (CGMPs) for dietary supplements.
- The current good manufacturing practices (CGMPs) final rule will require that proper controls are in place for dietary supplements so that they are processed in a consistent manner, and meet quality standards.
- The CGMPs apply to all domestic and foreign companies that manufacture, package, label or hold dietary supplements, including those involved with the activities of testing, quality control, packaging and labeling, and distributing them in the U.S.
- The rule establishes CGMPs for industry-wide use that are necessary to require that dietary supplements are manufactured consistently as to identity, purity, strength, and composition.
- The requirements include provisions related to:

- the design and construction of physical plants that facilitate maintenance,
- cleaning,
- proper manufacturing operations,
- quality control procedures,
- testing final product or incoming and inprocess materials,
- handling consumer complaints, and
- maintaining records.
- To limit any disruption for dietary supplements produced by small businesses, the rule has a staggered three-year phase-in for small businesses. The final CGMPs is effective in June 2008 for large companies. Companies with less than 500 employees have until June 2009 and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

## **Interim Final Rule:**

- The interim final rule (IFR) establishes a petition process for a manufacturer to apply for exemption from the 100 percent identity testing requirements for dietary ingredients used in manufacturing dietary supplements.
- If a manufacturer is granted an exemption, the manufacturer would still be responsible for ensuring the quality of the final dietary supplement product.
- The manufacturer would have to provide data in its petition demonstrating that less than 100% identity testing does not materially diminish assurance that the dietary ingredient is the correct dietary ingredient.
- The IFR is effective in June 2008 when the CGMP final rule becomes effective. However, there is a 90-day comment period. Based on the comments received, the IFR may be revised.

## **Consumer Benefits:**

- Consumers should have access to dietary supplements that meet quality standards and that are free from contamination and are accurately labeled.
- The rule will give consumers greater confidence that the dietary supplement they use has been manufactured to ensure its identity, purity, strength, and composition.
- The rule addresses the quality of manufacturing processes for dietary supplements and the accurate listing of supplement ingredients. It does not limit consumers' access to dietary supplements, or address the safety of their ingredients, or their effects on health when proper manufacturing techniques are used.

## **Manufacturers:**

- Under the Dietary Supplement Health and Education Act (DSHEA), manufacturers have an essential responsibility to substantiate the safety of their products and for determining that any representations or claims made about their products are substantiated by adequate evidence to show that they are not false or misleading.
- The CGMPs will help to ensure manufacturers produce unadulterated and properly labeled dietary supplements.
- Under the CGMP rule, manufacturers are required to:

- Employ qualified employees and supervisors;
  - Design and construct their physical plant in a manner to protect dietary ingredients and dietary supplements from becoming adulterated during manufacturing, packaging, labeling and holding;
  - Use equipment and utensils that are of appropriate design, construction, and workmanship for the intended use;
  - Establish and use master manufacturing and batch production records;
  - Establish procedures for quality control operations;
  - Hold and distribute dietary supplements and materials used to manufacture dietary supplements under appropriate conditions of temperature, humidity, light, and sanitation so that the quality of the dietary supplement is not affected;
  - Keep a written record of each product complaint related to CGMPs; and
  - Retain records for 1 year past the shelf life date, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records.
  - Examples of product quality problems that the rule will help prevent are:
    - dietary supplements that contain ingredients in amounts that are greater than those listed on the label
    - dietary supplements that contain ingredients in amounts that are less than those listed on the label
    - wrong ingredient,
    - other contaminant (e.g., bacteria, pesticide, glass, lead),
    - foreign material in a dietary supplement container,
    - improper packaging, and
    - mislabeled
  - The interim final rule allows manufacturers to petition FDA for an exemption from the requirement of 100 percent identity testing of one or more dietary ingredients used in manufacturing the dietary supplement. The manufacturer would provide data to demonstrate that its proposed reduced frequency of identity testing does not materially diminish assurance that the dietary ingredient is the correct dietary ingredient. Each petition will be considered on a case by case basis.
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## **Emerson Quality Program (EQP)**

The EQP is a rigorous quality assurance program designed to provide practitioners with reliable information about the quality standards of participating brands in accessible, informative and succinct summaries.

We have carefully and comprehensively evaluated our EQP Silver and Gold Partners and attest that their manufacturing processes meet and exceed federal dietary supplement GMP, including:

- Product design
- Manufacturing controls
- Raw ingredient and finished product testing

