



## *POSITION STATEMENT*

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# **Dietary Supplement Good Manufacturing Practices Long Overdue; Mainstream Industry Ready, Willing and Waiting for GMPs**

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**Background:** When the Dietary Supplement Health and Education Act (DSHEA) was enacted in 1994, Congress authorized the Food and Drug Administration (FDA) to establish Good Manufacturing Practices (GMPs) modeled on food regulation but specific to dietary supplements. Notice of the proposed rule-making was issued in 1997 and a proposed rule was published in 2003. The final rule cleared FDA in late 2005 and was sent to the Office of Management & Budget (OMB) for review. **To date, the GMP rule has been stalled at OMB for more than one year, with no public explanation for the delay.**

### **Responsible Supplement Manufacturers Want the GMP Rule Published**

- Dietary supplements are regulated in the U.S. as a sub-category of foods as they have been for their entire history. Therefore, by law, they are subject to existing GMP regulations applicable to foods (21 CFR, Section 110). Current food GMPs have for many decades provided an adequate underpinning for the manufacture of both conventional foods and dietary supplements, and many companies already go beyond the procedures currently required by food GMP regulations.
- The final GMP rule will provide an appropriate model for new companies entering the industry and will most certainly raise the bar for all companies to rigorously and consistently produce quality products. Promulgation and proper enforcement of final GMP rules specific to dietary supplements is critical to the long-term growth of this industry.
- Supplement manufacturers want the final GMP rule published to level the playing field for all companies and to increase consumer confidence in the quality of supplement products available to the public.

### **Consumers Deserve Supplement-Specific Good Manufacturing Practices for All Supplement Products**

- Without a final GMP rule consumers question whether all companies are achieving the highest standards appropriate for manufacturing dietary supplements.
- The updated GMP rule would: enhance the current requirements regarding the cleanliness and proper maintenance of manufacturing plant facilities; ensure that plant personnel follow appropriate procedures and have adequate training; and guarantee that quality controls are in place to assure that raw materials are pure and uncontaminated.
- A final GMP rule—and enforcement of that rule by FDA—will assure consumers that all companies are abiding by these practices by law, and that companies that don't do so will face the consequences.
- More than 150 million Americans use dietary supplements each year. These products help prevent disease and promote good health as part of an overall healthy lifestyle. The institution of new dietary supplement GMPs will help companies better meet the needs and expectations of these consumers interested in improving their health.

### **OMB Should Release the Updated GMPs for Dietary Supplements**