FORMULATION TECHNOLOGY, INC.

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 96N-0417; Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements.

Dear Sir or Madame:

It was correctly observed in your own comments that "...dietary supplements may help prevent chronic diseases and maintain good health." As testament to this belief, *Prevention* magazine poll results produced an estimate that over 158 million Americans use dietary supplement products, spending $8.5 billion dollars a year. These consumers believe they are investing their money in health maintenance, rather than treatment of illness.

Americans taking dietary supplements are very enthusiastic about their health choices. While they want to be assured the supplements are pure and safe, they would also be very unhappy to find the supplements priced beyond reach. Accordingly, as observed in the preamble to your notice (68FR12158) FDA's proposals need to "...establish the minimum CGMPs necessary to...protect the public health." Excessively rigorous practices will make the use of dietary supplements prohibitively expensive to many Americans.

A major source of cost containment in this and all industries is competition. Competition comes in the form of small businesses. To illustrate how the new CGMP proposals will affect small to medium supplement manufacturers, consider figures derived from my company, Formulation Technology, Inc. Our typical order can be described by the following:

1. Our average batch size is 300,000 tablets
2. We typically produce 3000 batches/year
3. Our average number of ingredients/batch is 15
4. Ingredient total cost, in a batch, is $3000.00 to $4000.00

Analyses of both raw materials and finished product proposed in your CGMPs could add another $4500.00 to the batch cost. For dietary supplement manufacturers of very large batches, the proposed multiple analyses would represent an incremental increase in their batch costs. But for the small to medium-size manufacturers who keep the industry price-competitive, it could easily double their batch costs.

Dietary supplements are foods, comparable to fortified foods or functional foods. As with Food Industry GMPs, dietary supplement regulations should allow analytically-based Certificates of Analysis (CofAs) from qualified raw material vendors. But aside from mandating a raw material identity test, requiring each supplement manufacturer to analyze all his raw materials is excessive and unjustified. We therefore petition you to revise proposed analytical requirements to allow manufacturers to use CofAs.

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We agree with the intent of the proposed regulations to ensure identity, purity, strength and composition. But we also believe the costs of analysis and recordkeeping have been seriously underestimated. You propose strict recordkeeping on components, ingredients, supplements, packaging and labels. Companies that produce single ingredient products in one packaging configuration would have a much-reduced recordkeeping burden. But our company has many formulae with comprehensive vitamin and mineral supplementation, including trace mineral blends. Some formulae have as many as 30-45 active ingredients. Under proposed regulations these products would require more intensive, expensive recordkeeping and analysis than is perceived in your proposals.

In recent hearings on the proposed regulations, it was commented that 30% of small manufacturers presently use no CGMPs at all. We believe your efforts to reform the industry should focus on those manufacturers instead of penalizing companies like ours, already using food industry GMPs. In the several examples of industry problems FDA discussed in the proposed rule making (68FR12161-3) there were existing regulations already in place that could and should have prevented those problems, and vigorous enforcement of those existing regulations would effectively have gotten the attention of those bad actors. Perhaps you intend your proposals to address the bad actors by making dietary supplement manufacturing so expensive that only the largest of current companies will survive. This anti-small business posture was surely not the intent of the original legislation.

In summary, we support improved GMP regulations, but disagree with the rationale for having unique dietary supplement GMPs. We believe the FDA proposal overstates potential benefits of the new GMPs for dietary supplements and underrates the cost. Further, the proposed regulations are not likely to reduce recalls to zero or eliminate the need for active enforcement against irresponsible companies. An argument can be made that adequate enforcement of existing food GMPs would accomplish a lot, even in the absence on new GMPs for dietary supplements.

Respectfully Submitted,

Keith W Hensley

Keith Hensley
President
Formulation Technology, Inc.