PEAK NUTRITION

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April 2, 2003

To: Dockets Management Branch (HFA-305)
Food and Drug Administration
5830 Fishers Lane; Rm 1061
Rockville, MD 20852

From: Allyson Thoms; Operations Manager
A.T.
Peak Nutrition Inc.
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Subject: Public Comment on Docket No. 96N-0417; RIN 0910-AB88 Proposed Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

This letter is being written to provide comment to the Food and Drug Administration on Docket No. 96N-0417; RIN 0910-AB88 entitled the proposed guidelines of Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements.

The following overview comments are provided:

1. The original passage of DSHEA in 1994 stated that guidelines should be established and implemented by FDA that follow Food cGMPs. The proposed guidelines as they are currently written are not at all similar to Food cGMPs, but instead are very similar to Drug cGMPs. Thus, these proposed guidelines have gone far beyond what Congress had initially intended by the passage of DSHEA, since these proposed guidelines are not even close to Food cGMPs. These proposed guidelines are just another example of an increasing federal bureaucracy that limits growth and opportunities for small businesses and heavily favors large multi-national corporations.

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2. FDA currently has more than sufficient regulatory authority over the Dietary Supplement industry and additional regulatory guidelines are not needed at this time. What is needed is that FDA needs to enforce the current regulations that they have in effect and make non-complying firms either comply with current regulations or face regulatory action by FDA. Enforcement and not additional regulations would be the greatest activity that FDA could conduct to improve the quality of dietary supplements in the market and to better protect public safety and public interest.

3. The economic impact of implementing the new proposed cGMPs on Dietary Supplements to Peak Nutrition Inc, a "very small business" per FDA's guidelines would be devastating. Peak Nutrition is a very small business with annual sales of approximately $ 1,600,000 with four full-time and one part-time employee. The economic impact of complying with these new regulations would result in the closing of Peak Nutrition as a viable business and the loss of employment for five individuals (all of which are female employees with several being single parents or heads of households). Thus, the loss of this employment in a rural county area would be impossible to replace, where our average employee makes approximately $ 28,500 per year not including benefits.

In closing, FDA needs to consider the devastating impact that these new regulations will have on "very small businesses" and the economic loss in jobs and tax benefits that are obtained by these businesses in the USA. I believe that if new regulations are going to be implemented, then exceptions should be made for "very small businesses" within the USA.

Thank you for your time on this matter and I hope that you will consider my comments during your review process.

Allyson Thoms