"Quality You Can Trust"

K&K LABORATORIES, INC.

June 9, 2003

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Proposed Rule "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

Dear Madam/Sir:

I am writing to comment on the proposed "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements" rule. I have, and wish to express on behalf of my family operated supplement manufacturing business, serious objections to and concern about the CGMP proposed rule, both broadly based and in the particulars.

From the Proxmire Amendment to this date, the Congress of the Untied States has repeatedly acknowledged that nutritional supplements are not drugs and do not require a regulatory burden approaching that which public safety demands of the drug industry. The CGMP rule is an effort by so-called stake holders both within and outside government to override the the will of our elected representatives and impose a new set of regulations and an attendant bureaucracy upon this industry.

The only true stakeholders in this matter are the consumers. Millions of Americans chose to include one or more nutritional supplements in their daily diet. The hard-earned dollars they spend are an expression of confidence that these products benefit their lives, a well merited confidence in the quantity of the products they purchase, and represent an assertion that Americans have the right to choose what they will eat and drink without an overseer. All costs are ultimately passed on to the consumer. If the potential for harm that exists in even properly developed and prescribed drugs or in improperly processed foods existed in dietary supplements, then the CGMP rules would be worth considering. The risks from consuming dietary supplements manufactured

3305 TYLER STREET • CARLSBAD, CA 92008

(760) 434-6044

under current rules is nil, absent intentional misuse or abuse by consumers, and from that no product is immune and no degree of regulation is a sufficient deterrent.

Small manufacturers, like K & K Laboratories, have a key role in the nutrition industry. We supply the smaller brands that compete with the big manufacturing companies, which help keep prices down and consumer choices varied. The excessive burden of an extensive new, high cost for low benefit regulatory framework will run some manufacturers out of business and force those remaining to pass costs on to consumers. Large manufacturers cheerfully accept the burden of new personnel mandates and pyramids of paperwork with the knowledge that what is a ripple in their pond is a tidal wave for the little guy. This premise would seem farfetched if not for the fact that the giants of our industry have already been found to have colluded to fix prices, and have been compelled to pay large settlements. Likewise, the distributors of nutritional products may like the publicity boost the CGMP rule would give them, but will not bear the costs unless they also manufacture.

The notion that is suggested in the publication of the proposed rule that small and medium sized manufacturers in this, or any industry for that matter, are begging for additional regulation is laughable and betrays authorship by one totally unacquainted with the entrepreneurial mind and the struggles of running a business and earning a living in the free enterprise system.

An area of controversy in the nutritional industry is the sale and use of ephedra products. The government permits the sale of tobacco, alcohol, rat poison and a host of other products that have no, low or high utility, but are potentially deadly if abused. If ephedra is one of these, its availability ought to remain as it is. If ephedra is a dangerous drug like marijuana, it ought to be banned. The most wrongful use of ephedra would be for uncertainty about it as a consumer product to be leveraged into the rationale for a new costly bureaucratic empire regulating vitamin C, thiamine, calcium, garlic and the whole range of nutritional products universally recognized as safe.

The only cost effective system for identity testing is for it to be performed by the manufacturers or importers that first sell the raw materials in the United States. If necessary the certificates of analysis that are commonly used could be converted into sworn affidavits. Testing a 25,000 kilogram lot of riboflavin once when it is still in one location is less costly than requiring that the same test be performed on every 25 or 250 kilogram shipment sent out to a number of tablettors. Additionally, it is best to identify a problem or discrepancy at its earliest stage.

In conclusion, the incredibly high degree of safe consumption of nutritional supplements demonstrates that the statutory and regulatory authority that the FDA currently possesses is adequate. The risks cited in the justification for these regulations are theoretical or hypothetical. The questions not asked in the proposed rule are about how many people have died in the last 10 years because of the vitamins they take? How many of these, if any, would have been saved if the proposed rule had been in place? How much will the rule cost taxpayers and consumers? Accurate answers to these questions would reveal that the CGMP has, at its core, regulation and bureaucracy for its own sake.

Thank you for your consideration.

Respectfully submitted,

Alex Kononchuk
President