

**Robert G. Kavanaugh, B.S.C CPA**

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

RE: 96N-0417

A "very small business" owner's comments on the impending finalization of the cGMP for Dietary Supplements.

Dear Sirs:

**Implementing the proposed cGMP for dietary supplements (as currently drafted) would have the single undesired effect of destroying small business, while increasing 'unlawful' unscrupulous business practices. A primary goal of any FDA regulation should be to increase and encourage compliance through a co-operative and participatory regulatory environment, fostering trust rather than fear of the presence of an FDA inspector. Small business is the genesis of innovation and, in what has historically been a very innovative industry, the concerns of small business should not be so capriciously disregarded.**

As a small business supplier of dietary supplements--and based upon my review of the 120 page NNFA comments document (hereinafter "the comments") submitted to FDA regarding proposed cGMP for dietary supplements--I am gravely concerned about what I anticipate will be the end and destruction of most or all 'legitimate' very small business participation in the dietary supplement industry. In addition, I predict that the cGMP, if released as is, without a completely different approach to the work product, will result in a dietary supplement industry so hostile to the regulatory environment that results, that rather than improving the safety, efficacy and proper labeling of dietary supplements, the cGMP will, in the aggregate, result in a food supply with an extraordinary number of health and safety weaknesses resulting from the formation of clandestine, unregistered, unlicensed, wholly non-compliant small manufacturing enterprises as well as increased reliance upon cheaply manufactured and imported ingredients from bordering countries. If history is at all predictive, (and it is) I foresee a regulatory environment analogous to that which US Treasury agents experienced in Chicago after the enactment of prohibition.

Based on my many years experience in the dietary supplement industry and on my experience as financial and empirical analyst with one of the nation's largest consulting firms, and based upon my review of the comments in the document submitted by NNFA, **I am highly skeptical of FDA's empirical assumptions with regards to the costs of implementing their proposals.** (FDA's cost assumptions with regard to micro-biological testing costs are so understated that if it were a criminal offense for Federal Agents to lie to industry members--as is the case inversed--your published work product might have been considered an indictable criminal offense analogous to the egregious misfortunes of former Metabolife executives.) The dietary supplement industry cannot be expected to embrace and comply with FDA's flawed regulations when such dubious empirical assumptions are the basis and justification for subsequent conclusions that form the remainder of the work product. The benefits of final cGMP cannot be based on the flawed empirical assumptions. The inexcusably large difference between FDA's

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understated PROJECTED costs and the ACTUAL costs of implementing FDA's highbrowed, statistically unnecessary "100% finished product batch testing" requirements will be bourn by real people when jobs are lost unnecessarily, and by real consumers when the price of their dietary supplements skyrocket while their choices are diminished by an increasingly limited selection.

What is the problem FDA is attempting to correct? What was the spirit of the law passed by Congress? I urge FDA to reconsider and reaffirm what the primary objective of implementing these regulations is and design a practical, real-world, cost-effective solution to the problem, if any, FDA is proposing to correct. Do not simply implement overly conservative, economically impossible regulations that will simply result in mass non-compliance and the creation of an "us and them," relationship with FDA inspectors in the real-world-day-to-day-business of protecting our nation's food supply.

FDA's "Zero Defect/Total Quality Assurance" cGMP approach to regulating the dietary supplement industry will create a future with two distinct groups of dietary supplement manufacturing and distribution firms, and in my opinion, neither class of firm will result in achieving a safer food supply nor a healthier population:

**FIRM 1 – The Very Large Licensed Dietary Supplement / Pharmaceutical Manufacturing Firm.** These firms will resemble ADM, Roche, Smith Kline Beecham and Pziser and will make homogeneous, homogenized, wholesome, wholly over-processed, chemical fractionates of what once might have been some potentially beneficial nutritional component of a food, compressed precisely pursuant to the appropriate pressure specs and properly coated with pleasant polished powdered sugar. No fear of bacteria here. Louis Pasteur would have been so proud. Contests will be held for employees who can find even a single microbe inside these gleaming monoliths and a new *Lexis*® will be awarded to anyone isolating a pathogen inside these filtered-air-chambered, sterilized halls! (Meanwhile after 20 or 30 years of a comprehensive FDA crackdown on non-compliant firms and highly successful enforcement, prosecutions and mandated Federal prison terms have locked up all the bad little microbe and dirt pushers, epidemiological studies will have determined that certain levels of microbiological, naturally occurring in the food supply were a critically important part of biological functioning in man and animals, and the absence and elimination of exposure to "microbes and dirt" ultimately led to higher incidents of immune-compromised illness and disease . . . and gosh, who would have considered this--since it only took our cells about a kajillion years to evolve (right along side all that nasty dirt and bacterial) into what many of us try to pass off as human—that most of nutrients our cells need are derived from food interacting with healthy colon flora<sup>1</sup>-- to remain intact and healthy.

**FIRM 2 – The Very Hidden, Non-compliant Clandestine and Foreign Manufacturing Firm** not unlike that of the "beer, wine and spirits industry" in Chicago right after prohibition! I have had experience with firms counterfeiting my own dietary supplement products. The "firm" is probably not using any testing methods and they are certainly not registered with the State or FDA. In fact, I have contacted the FDA almost a dozen times about this dangerous counterfeiting operation but have heard of NO ENFORCEMENT ACTION! **Now, if the FDA cannot handle the volume of unscrupulous and unregistered dietary supplement "firms" now, why are they proposing new regulations which will undoubtedly create a very large number of new clandestine operations?**

FDA cannot simply disregard the serious financial impact and burden these proposed rules will thrust upon small businesses. To do so would be to ignore human nature. The

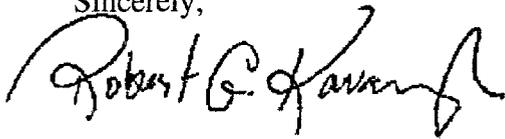
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<sup>1</sup> **Flavonoids and isoflavones: absorption, metabolism, and bioactivity. Free Radical Biology and Medicine Volume 36, Issue 7 , 1 April 2004, Pages 827-828**

fact is that people are going to continue starting and running small businesses and making and shipping dietary supplements in interstate commerce, but they will locate in buildings with foil lined windows and closed and locked doors. They will not register with the FDA nor will they register with the States in which they reside. The most innovative (and egregious) may even work from their homes and garages. I can't wait until FDA implements those new cGMPs, I mean wouldn't we all be better off in a world where guys are making vitamins right there next to their cars? Okay, maybe not. . .

I urge FDA to consider these factors before issuing their final cGMPs for dietary supplement manufacturers. Should you wish to discuss anything in this letter, please feel free to contact me at 714-642-1803.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert G. Kavanaugh". The signature is fluid and cursive, with a large initial "R" and "K".

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