

Med-Tox Group

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Thomas N. Tiedt, Ph.D. | PO Box 9261, Bradenton, FL 34206 | 941-744-9397 phone/fax

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

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

Dear FDA:

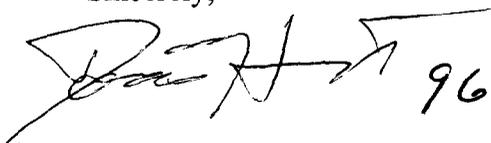
My company fully supports the establishment of current good manufacturing practices (cGMPs) rules for dietary supplements.

However, as a member of NNFA and having reviewed hundreds of thousands of pages of documents pertaining to the manufacturing of herbal supplements, virtually everything NNFA and herbal supplement companies are entering into this docket is a hoax.

NNFA's and other supplement trade associations' GMPs have proven to be shams. Two weeks ago in a Congressional hearing pertaining to ephedra supplements, the public could get a glimpse of the serious manufacturing problems perpetrated by the herbal supplement industry. Company executives know virtually nothing about their products. Although asked to be prepared by Congress, company executives could not address their purported quality control measures. Metabolife, for example, did not know that the bovine complex of Metabolife 356 actually referred to testicles, prostate glands and uterine tissue. NVE testified that it had not idea how Viagra was added to supplements it manufactures. It also became clear that leaders of herbal supplements are methamphetamine felons now turning to supplements to sell stimulants and controlled substances, including banned horse stimulants.

FDA should not water down or reduce the proposed GMPs. If anything, they should be enhanced with further mandatory testing, minimum requirements for quality assurance and control staff, and requirements that all aspects of DSHEA be followed, including that per-market safety and efficacy testing is accomplished and only dietary substances are sold as dietary supplements. Coca leaves, marijuana, opium, Chinese ephedra and testicles are not dietary supplements. Assuring the absence of heavy metals, pesticides, adulterants and banned drugs should be required.

Sincerely,

 96N-0417

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