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September 22, 2003

Mark B. McClellan M.D., Ph.D.
Commissioner of Food and Drugs
FDA
5600 Fishers Ln
Rockville, MD 20857

Dear Mark:

I am writing to inform you of my substantial agreement with the comments of Essential Nutrition *et al.* regarding the Food and Drug Administration (FDA)'s March 13, 2003 proposed rule for dietary supplement Good Manufacturing Practices (GMPs) (Proposed Rule) and to support implementation of the changes that those comments recommend. I also wish to express my agreement with the economic analysis of the Proposed Rule performed by Dr. Paul Rubin.

I am concerned that the Proposed Rule is based upon flawed economic reasoning and could negatively impact the supplement market without creating any actual increase in public safety. I am also concerned about possible anticompetitive effects of the proposed rule. In addition, by prescribing methods of manufacture rather than simply prohibiting practices that are likely to cause harm, the rule discourages innovation in safety technology.

The FDA has estimated that the Proposed Rule will annually cost no more than $86 million, however, information provided to my office indicates the actual costs could be as much as ten times the FDA's estimates. Furthermore, the FDA estimates that the Proposed Rule will create annual benefits valued at $216 million, whereas information provided to my office estimates the actual annual benefits at no more than $13.9 million. Moreover, small businesses will likely bear a disproportionate burden under the Proposed Rule, and the consuming public will not likely see any real improvement in the relative level of safety of products in the market.

Concerns have also been raised regarding the FDA's assumptions and conclusions. For example, the FDA's economic analysis contains the assumption that there would be no recalls if the Proposed Rule were in place. This is a questionable assumption in light of the frequent recalls in the drug industry where GMPs have been in place for years. See, "New Prescription for Drug Makers: Update the Plants," The Wall Street Journal (September 3, 2003).

The Proposed Rule is modeled after the drug GMPs despite the directive from Congress in the Food, Drug, and Cosmetic Act that dietary supplement GMPs, if adopted, be modeled after the food GMPs. 21 U.S.C. § 342(g)(2). Moreover, as recently reported in the September 3, 2003 *Wall Street Journal* article "New Prescription for Drug Makers: Update the Plants," the drug GMPs have stagnated innovation in drug manufacturing methodology resulting in inefficiency and recalls throughout the pharmaceutical industry. Following Congress's direction to use the

food GMPs as the model for dietary supplement GMPs is the legally required (and the better) way to proceed.

The Rubin Report concludes that the adverse economic effects of the Proposed Rule will fall hardest on small firms. Because the regulatory costs that the Proposed Rule requires for compliance are independent of the size of the firm, they will disproportionately impact on small firms. Moreover, the Proposed Rule will likely reduce demand for, and sales of, supplements because increasing costs will cause increasing prices for consumers. The reduced demand is exacerbated in small firms because their per unit costs are disproportionally increased by the fixed regulatory costs.

FDA should implement the following changes to the Proposed Rule: (1) limit enforcement action against parties who violate GMPs to instances in which FDA proves that a dietary supplement presents a significant or unreasonable risk of illness or injury when used as recommended or suggested in labeling in accordance with 21 U.S.C. § 342(f)(1)(a)(i)(ii); (2) eliminate all ambiguities that invite the exercise of unbridled discretion by enforcement officers; (3) expressly protect trade secrets and confidences; (4) postpone the effective date of the Proposed Rule for 24 months after its adoption to permit a voluntary inspection and compliance program that will lessen the economic impact of the rule; (5) approve a program where FDA shall issue certificates to companies found to comply with the GMPs that may be placed on product labels creating a free market incentive for compliance driven by consumer preference for certified products; (6) state that suspected violators whose products do not present a significant or unreasonable risk of illness or injury will be given notice of potential violations and an opportunity (with reasonable deadlines) to come into compliance using mutually agreed upon means that minimize the economic impact on the subject; (7) affirmatively state that record-keeping and documentation violations of the GMP rule will not result in enforcement action and will not result in the subject's products being deemed "adulterated;" and (8) place testing requirements only upon source manufacturers and allow finished product manufacturers, packers, holders, and others "down stream" to rely upon certificates of assurance from the source manufacturers so long as they can show adherence to a chain of safe custody.

Efforts to protect the safety of dietary supplement products do not have to be the ruination of small businesses in this industry. If the dietary supplement marketplace is reduced to only those large scale manufacturers that can meet the burdens of the Proposed Rule, the competition in the marketplace will be minimal and market entry will be near impossible. I therefore respectfully request that the FDA act to preserve competition, and innovation, in the dietary supplement industry by adopting my proposed changes to the Proposed Rule. Thank you for your consideration of my request.

Sincerely,

Ron Paul

Ron Paul