CONNECTICUT PHARMACISTS ASSOCIATION

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Food and Drug Administration
Dockets Management Branch
Room 1061
5630 Fishers Lane, Rockville, MD 20852.
Center for Food Safety and Applied Nutrition Director Joseph Levitt

April 3, 2003

Re: FDA To Publish Dietary Supplement GMPs

The Connecticut Pharmacists Association represents the pharmacists in the State of Connecticut. As health care providers, we would like to respond to the recent announcement of the upcoming release of proposed rules governing good manufacturing practices (GMPs) for dietary supplements. We agree that this is not only an historic move in dietary supplement regulation, but is long overdue.

We would like to lend our full support for these new regulations. These products have gone far too long without the quality assurance and peace of mind, which the FDA provides, potentially putting every patient at risk.

The public deserves at least a minimum standard that quality control procedures exist for dietary supplements to ensure they have not been adulterated with contaminants or impurities. We also agree that these products need to be properly labeled to accurately reflect both active and inactive ingredients contained in the product using the same standards used for other over the counter products thereby proving consistency in the industry.

Although not always recognized by the general public, these products do contain powerful drugs and therefore should fall under the same kind of rules and regulations that are required for all drugs. Although these proposed rules probably will not address the determination of efficacy of these products, it is the first step in providing some assurance to the consumer. These potent drugs (such as Ephedra) cannot remain ignored by the industry as they carry the potential for causing great harm.

Because these products are available over the counter, there is rarely assistance from a health care professional for the selection and advice on these products. This increases the potential for both misuse and adverse drug reactions for these self-medicated individuals. However, with no approved indications for use, the public at least deserves the consistency from batch to batch and brand to brand that they rely on today with FDA approved products. This is a major step in the protection of the public and an advance for the supplement industry.

95N-0304 C3969

Thank you for finally addressing this issue and providing our patients with the confidence that the FDA approval process brings to them.

Sincerely,

Margherita R. Giuliano, R.Ph.
Executive Vice President
Connecticut Pharmacists Association