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

Docket No. 96N-0417
Good Manufacturing Practices for Dietary Supplements

These comments are submitted by Pharmanex, LLC., a division of Nu Skin Enterprises Inc., a distributor of dietary supplements headquartered in Utah. Pharmanex has been actively involved with the Utah Natural Products Alliance (UNPA) in developing the attached response regarding the FDA's proposed good manufacturing practices (GMPs) for dietary supplements. We support the recommendations presented by UNPA and include our own additional comments.

Pharmanex also wishes to express our strong desire to implement GMPs for dietary supplements, but has concerns with the GMPs proposed by the FDA and the justification used for explaining why the FDA deviated so drastically from food GMPs. Pharmanex asserts that the proposed GMPs are not modeled after food GMPs as statutorily mandated by Congress in DSHEA.

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It is our opinion that the FDA has greatly underestimated the financial impact of the proposed GMPs on the dietary supplement industry and underestimated the number of companies that will be forced out of business. For Pharmanex, we estimate the increase in testing required will double the cost of our finished goods. The GMPs as proposed will make it so onerous to manufacturers that many companies with an international presence will choose to move all manufacturing out of the country, thus impacting local manufacturers, raw material suppliers and testing laboratories, and resulting in the loss of revenue and jobs. Furthermore, the costs of implementing the proposed GMPs would be ultimately passed on to the end consumer discouraging dietary supplement use.

As with foods, dietary supplements include a large variety of finished goods. The Advanced Notice of Proposed Rulemaking (ANPR) (FR: 2-6-97) was general enough to encompass all dietary supplements while allowing for good quality systems to address the various forms of processing. It is our opinion that the final GMPs for dietary supplement should be more similar to the ANPR then the proposed GMPs.

Finally, Pharmanex does not agree with the FDA's assertion that GMPs are necessary for preventing adulteration in dietary supplements. As with other industries, the dietary supplement industry requires GMPs to assure

that finished products are manufactured according to quality procedures not to prevent adulteration. Pharmanex supports thorough testing of incoming raw materials, manufacturing with quality procedures and sample testing finished products according to appropriate statistical methodology. Pharmanex requests the opportunity to present additional information within 30 days after the comment period closes.

Sincerely,

Pharmanex, LLC., A Division of Nu Skin Enterprises, Inc.

Gordon Fralick
Sr. Manager of Global Regulatory Affairs