State of Utah

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DEPARTMENT OF COMMUNITY AND ECONOMIC DEVELOPMENT

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August 8, 2003

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

Dear Sirs:

The Utah Natural Products Alliance has asked the Utah Department of Community and Economic Development to review the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements; Proposed Rule published in the Thursday, March 13, 2003 Federal Register out of concern that the proposed regulations will have a significant impact on their operations.

As background, the nutraceutical industry in Utah is composed of approximately 165 businesses, with 5,700 direct employees at an average salary of $39,000 per year. It has a total impact of $1.6 billion to the Utah economy, 12,000 jobs, and generates some $94 million in total state and local government revenue annually.

After receiving comments and supporting data from members of the UNPA, which they will be forwarding to you in more detail, we agree that some of the assumptions used in the analysis of the proposed rule raise serious concerns. Our concerns center on four areas:

1. Scope. The following statements are made in the Analysis of Impacts; "the proposed rule requires only tests for identity, purity, quality, strength, and composition of the final product", and "tests on incoming components and inprocess tests would not be required by the proposed rule". The UNPA disagrees with these two statements. Although difficult to quantify, on the basis of comments received, we estimate that the adjustment to the testing costs made in the analysis may underestimate the scope of the required testing by as much as 50%.

2. Cost per Test. The consensus among representatives of the dietary supplement industry in Utah is that the cost per test would average in the $100 - $120 range rather that the $60 used in the baseline analysis.

3. Tests per Batch. The average for firms submitting data to us was almost 14 tests per batch, as opposed to the three (3) used in the baseline and six (6) in the Sensitivity of Costs analysis.

We do not consider that the companies representing the dietary supplement industry in Utah are all extreme outliers. Therefore, after reviewing the (preliminary) data that will be submitted to you and adjusting the above three factors based on the Sensitivity of Costs analysis table, we believe that the true cost of the proposed regulations would be some $350 million per year rather than the $86 million baseline, and could be double that if all the high-end estimates proved true.

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4. Benefits. Fully 50% of the imputed benefits to consumers were the result of "reduced hypothetical search costs as a measure of the benefit from increased assurance of quality". In our opinion the benefit to consumers, and by extension to the industry, of reduced search costs resulting from an increased confidence in the quality of the product is more than outweighed by a fairly high price sensitivity on the part of consumers. We would estimate a range of 1.0 to 1.2, based on data provided to us by companies in Utah and from reviewing other price sensitivity studies of consumer goods.

In sum, it seems likely that the effect of the increased costs resulting from the Proposed Rule would be to turn the possibilities listed in the analysis to probabilities: prices for consumers would rise significantly; production would be moved off-shore; and some manufacturers, particularly small companies, would go out of business entirely. In our opinion, this would more than offset the benefits intended by the proposed regulations.

We urge the FDA to consider the additional data and input generated by this Proposed Rule to produce GMPs for dietary ingredients and dietary supplements that will achieve the desired health benefits for consumers while maintaining the vitality of a significant sector of both, the Utah and national economies.

Sincerely yours,

David G. Harmer
Executive Director

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