National Vitamin Company, Inc.

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To FDA Dockets Management Branch 03 3 '03 JUN 19 A10 :05

National Vitamin Company has approximately 200 full time employees with annual sales between $20 and $30 million. National Vitamin Company manufactures Nutritional Supplements, OTC's and Cosmetics. We are a solely owned firm with 2 plants. Our data and concerns deal with the Nutritional Supplement side of our industry. We believe cGMP's are necessary, but that the proposed regulations will cost our company more than what the FDA projects and that there is room for adjustment. We offer our estimated yearly costs of implementation, proposals of our own, and questions regarding the proposal.

Due to the time consuming and expensive process of analytic testing, especially with multivitamins/minerals, we suggest the testing of an active ingredient premix. With this, we would be able to make a large enough premix, test the premix once, and be able to use the premix in our formulas when needed. This would save multivitamins/minerals from having to be tested every batch, which would be cost and time effective.

We disagree with the estimation of implementation for a small business to be around $60,000 per year. Implementing the proposal for our top 45 sellers would cost $131,314 in assay costs from an outside lab, and $6440 in annual interest due to the increased inventory that maximum batch sizes would require. Maximizing batch sizes would be necessary to minimize the costs of analytic testing. The annual implementation cost would be $137,754 for our top 45 sellers, and estimated $275,508 for implementing the proposals on all of our products.

If we were to do all of our testing in-house, the costs would still exceed $60,000 per year. Three additional chemists would need to be hired to perform the testing at $50,000 (includes overhead) per year. Three HPLC's would be needed at $45,000 each, with testing supplies at $5,000 per HPLC. One UV-Vis at $20,000 and an ICP at $100,000 would also be required. Labotory enlargement to hold the new equipment would cost an additional $20,000. The total initial cost in equipment and lab enlargement would be $290,000 with a $150,000 in labor per year.

Whether having the analytic testing done in-house or sent to an outside laboratory, the costs will be extreme and considerably higher than the estimated costs per year.

Questions regarding the proposal: Will dissolution testing be required per USP, since the Nutritional Supplement industry is regulated under foods? Can we justify a final product expiring in three years, if one of the ingredients expires in less than three years? Also, will items such as Rosehips, which there isn't a valid testing procedure, require any testing, or will a verification of content in the final product suffice?

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Tom Rumolo, Technical Director

6/11/03