Shamanic Tonics
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Dear F.D.A.,

We would like to reply to the proposed GMP's.

As a very small business, these regulations would cost us roughly $10,000.00 a year. With our current profit margin, this would effectively put us out of business. We do not believe that this is the intent of the proposed GMP's.

Although we use contract manufacturers and buy tested (low pesticide, industrial pollutant, microbial and heavy metal count) extract ingredients from recognized suppliers, the new regulations would still exclude our products.

There are several ways it seems the overall quality and safety of dietary supplements could be improved without forcing so many small businesses in this country out of business. We also have an interest in maintaining public confidence in not only our business but in the industry as well.

For one thing, forcing manufacturers to lab test both each raw material and the finished products creates an unfair advantage not only large for manufacturers but also for those who produce single ingredient products. Mixed product 'formulas' would cost a great deal more to produce under the new regulations. This is especially true if the manufacturers produce small batches (as many small companies do).

One example of a way to deal with this inequality in the marketplace is shown by the Calif. Proposition 65 requirement for warning labels (regarding heavy metals), which only applies to companies with over 10 employees. Of course smaller companies still need to have acceptable levels, but the law recognizes that they are at a disadvatage and works with them to enable them to contribute to the diversity which makes the free-market system so viable. We feel that a similar clause could provide for the welfare and wellbeing of smaller companies who are striving to produce quality products and

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remain in compliance with continually evolving FDA regulations.

If a company buys raw materials from a GMP producer (who supplies certificates of analysis) and lab tests only the finished product to show that the label claims are met and not unreasonably exceded, as well as that microbial, pesticide, industrial pollutant and heavy metal counts are in acceptable levels, that should be sufficient to protect the public safety. In this scenario, the products would be filtered through two levels of testing but the cost of this would be shared by raw material producers and the manufacturers. Of course the manufacturers would have the ultimate responsibilty so it would naturally behoove them to test raw material before production, especially of large batches. Also, aside from standardized nutraceutical and nutritional ingredients, many herbal ingredients are best (and sometimes only) tested for quality by organoleptic (taste, smell, appearance) means.

Some of the most dangerous finished products seem to be imported ones which are purposely mislabeled, so domestic products should perhaps not be held to a higher standard than imported ones, which are sometimes not tested at all, either in the raw material or finished stages.

In addition, we feel the the proposed regulations on the holding of herbal products should more clearly specify either raw materials or tested and sealed finished products. For those of us who use contract manufacturers the new regulations would still exclude us from holding even tested and sealed finished products outside of a GMP facilty. These products have been specifically manufactured to be held and transported in a variety of conditions so we feel factory sealed finished products should be excluded from the regulations on the holding of products.

Thank you for your time, Edward Turpin

8/4/03