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31 July 2003

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

Dear FDA,

I submitted our comments electronically on 29 April 2003, but I have not seen them posted to the web site. Today I saw that the electronic comment portion for dockets was temporarily out of order, so I wanted to send a hard copy to make certain our comments were received for review and incorporation.

Comment on Docket ID 96N-0417, FR Doc. 03-05401
Proposed Rule for Current Good Manufacturing Practices for Dietary Supplements and Dietary Supplement Ingredients
21 CFR Parts 111 and 112

The Heritage Store is a "very small manufacturer" of natural dietary supplements in Virginia Beach, VA. We manufacture thirty-five (35) different supplement products in less than 8,000 square feet. We are a low-volume manufacturer. The average number of units sold per dietary supplement is 1200 per year. We generate ~$314,000 in gross sales from about 150 batches of dietary supplements. A review of the proposed regulations reveals a much larger impact on the consumer and us than your estimates indicate. In fact, it appears the proposed regulations are based on the drug CGMPs and that they are designed to close down very small businesses like ours and eliminate the specialty products that we make available to the public.

Here is a summary of costs as we have determined them for our company. More detail and discussion is found below. Our projection for annual testing costs is $67,400. We estimate needing $10,000 to add

the capability of lot numbering to our production line. We further estimate $50,000 in expense for larger capacity tanks/mixers and ancillary equipment. Our estimate for additional hours, staff, and training required to fully implement and maintain the proposed regulations would be at least $25,000 per year. Finally, our estimate for the cost of off-site storage is $20,000 per year. This is a total of $172,400 with annual expenses continuing at $112,400. This is grossly different from your estimates of first year cost being $62,000 and subsequent years being $38,000.

The products we mainly deal with are agricultural commodities and have a fair amount of variability from crop to crop. Many of our supplements use tinctures or other extractions from certain plants and are labeled as such. They do not make claims that they contain a standardized amount of compound X. For that to be particularly meaningful to the consumer we would need evidence that compound X had a particular affect or benefit to the body. (For example the salicin in willow bark that used to be taken for headaches). For us to pursue that line of reasoning we would need to treat them as new drugs and spend a lot of money and time in determining that and then we could make application to the FDA for drug claims. However, dietary supplements are not intended to be drugs or substitutes for drugs. They are meant to supplement the diet. Diets around the world and through time have been extremely diverse and our customers want the choices to supplement their diets with safe food supplements. Most of our customers have an inherent dislike for the extremely processed and single compound drugs that are available. They believe that many natural sources have small amounts of compounds that work synergistically together with a good diet and exercise to provide the body what it needs to sustain itself in a healthy fashion. Hence, our agreement that the supplement GMPs should be based on the food GMPs and not the drug GMPs.

DSHEA called for the GMPs for Dietary Supplements to be based on the food regulations and not the drug regulations. But a review of Docket No. 96N-0417 indicates that the FDA decided to propose CGMPs for dietary supplements based on 21 CFR 211, the drug regulations. The current proposed regulation is almost as costly and restrictive as the drug GMPs, except for a very few minor variations. It is far from the framework of the food GMPs. We welcome a level playing field and clear standards for all dietary supplement manufacturers to follow.

These are good for business and the consumer. However, recall that DSHEA was a response by Congress to the FDA wanting to regulate dietary supplements as drugs. The public organized and appealed to Congress and they created DSHEA as a response. Their position was that an informed consumer should be able to have choice in the market place for a variety of dietary supplements that are safe. During the nine years that it has taken the FDA to issue this proposed regulation, dietary supplements have shown themselves to be incredibly safe. The market and sales have grown tremendously and illnesses and deaths from improperly prepared food far outnumber those for dietary supplements. We acknowledge some supplements have had adverse interactions with drugs, but so have grapefruit juice and other foods. This is but one of many reasons that it makes sense to regulate them no more harshly than foods. While much of the proposed regulation is comprised of standard good practices in major food industry, the testing and control procedures in particular are oppressive and will greatly affect our business. That is, not allowing us to accept concentration values and identity based on supplier COAs will be very costly. At the end we propose that testing requirements be modified.

You overstate the benefits and grossly underestimate the economic impact. For the benefits you use ~$76/hr for your hourly wage in determining your statistical day. (Note: this is ~ seven times the value based on average per capita income from the Census Bureau.) However, for cost you use $15.65/hr. The cost might be on target with the minimum wage being <= $7.15/hour and with the cost of benefits being added into the figure. However, production of dietary supplements takes more than unskilled labor and this value is probably low for the industry. But these two things combined greatly skews the benefit to society. Before buying the statistical day argument, I would like to see you establish a comparison of the current risks of death and injury from supplements, drugs, food, and illness. If more people die from drugs, illness or food each year than from dietary supplements, then it would not seem appropriate to base it on a high risk job as you state in your document. Also, on page 439 you assume that the actual number of illnesses is 100 times what is reported. Our customers are very quick to report any change in color, taste, or affect our supplements have on them, so I find this a very high number. Plus, it is factoring in anecdotal data. Just because someone takes something and their cold goes away or they break out in a rash or they get a headache does not mean that

the supplement they took this morning is what caused it. Supplements are not allowed to use anecdotal evidence in their marketing, so I don't think anecdotal illnesses should be used in the calculation of the benefits of placing more regulations on them. On page 440 you seem to expect to see recalls falling to zero and wanting to include that in the benefits. Obviously there are a lot of food, drug, and cosmetic recalls every month and their regulations have been implemented for years. And on page 443, decreased search time for the consumer is mentioned as a benefit of having the industry using the same framework of regulations. This regulation is not expected to affect our clients when it comes to that. Our clients are atypical and do a lot of research regarding health and health products and this is not going to answer the questions that I get or our customer service representatives get, so I expect little or no effect regarding search time for the consumer.

We want to comment on some of the specific shortcomings of the estimates as summarized on page 429, and pages 433-434.

There are a couple of items in Table 14 on page 429 that do not reflect the impact on our company. First, our thirty-five dietary supplements have an average of five dietary ingredients listed in their supplement facts boxes. This is 25% more than your all other categories value of 4 that you used in your calculations. Finally, the one with the most impact is your estimation that the costs per test would be $60 on average. The tests that we will need to add to be in compliance are in the $75 to $200 range with $100 probably being a fair estimate of an average cost. This is contingent on there not being any need for method development and that analytical standards are readily available at reasonable expense. This represents at least a 67% increase financial impact of the cost of testing. Our projection for annual testing costs is $67,400, which is 177% of your projection for a very small facility. And our 144 batches per year are 65% the number in your estimates for a very small manufacturer. This means that the impact on other very small manufacturers is most likely even greater.

Table 15 on pages 433 and 434 summarizes the values used in cost calculations and we would like to comment on several items. We are a very small establishment and have 7,700 square feet of production and warehouse space. This is much less than your value of 24,674 square feet. Given the ratio of our number of batches per year from above, from

your estimates we should use twice as much space. This is further complicated by the fact that the bulk of our business is from our production of cosmetics in this same space. With small batches and small apparatus we are able to heavily utilize our small space. However, many aspects of the proposed regulation will push us to scale up our batch sizes and the larger equipment will require more space. Also, quarantine/hold areas will need to be greatly enlarged and raw materials purchased in larger bulk quantities. Also, we do not have unused space available for expansion. If we were to continue manufacturing these dietary supplements we would need to relocate the manufacturing facility. We estimate needing $10,000 to add the capability of lot numbering to our production line. We further estimate $50,000 in expense for larger capacity tanks/mixers and ancillary equipment. The only solution we currently have for the increase in square footage would be to rent off-site storage. We estimate that cost for an additional 2,000 square feet of space that is climate controlled to be $20,000 per year.

Another expense is personnel. We currently have a part-time quality department of one person. Enacting these proposed regulations would necessitate increasing hours and hiring someone else. Our estimate for additional hours, staff, and training required to fully implement and maintain the proposed regulations would be at least $25,000 per year.

An example of how to remedy the regulation is found in the Food Labeling Guide: Chapter V Nutrition Labeling. Question 39: "How many **samples** must be **analyzed** to determine the nutrient levels for a product?" Answer: "The number of samples to analyze for each nutrient is determined by the variability of each nutrient in a food. Fewer analytical samples are generally required for nutrients that are less variable. The variables that affect nutrient levels should be determined, and a sampling plan should be developed to encompass these variables."

This does not imply in any way that every ingredient of every batch produced needs to be tested. It implies that in order to have truthful labeling, the nutrient level should be tested and its variability determined, and from that a testing plan be developed to ensure that the labeling is accurate. Not every orange that weighs 100 grams will have 53.2 mg of vitamin C, but if a typical or average one does then it would be fine to

label the orange with that information. In fact, on page 345 of the proposed regulation you state "Plant or animal ingredients are likely to experience greater natural variation in product quality than synthetic compounds...". This is similar to natural food, and we feel that dietary supplements should be treated the same.

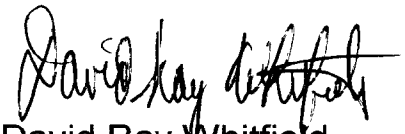
Infant formula nutrient testing in 21 CFR 106 also sheds some light. Nutrients from premixes do not have to be retested and the final product does not have to be retested for those nutrients. Part of the reasoning surely is that the batch records provide controls and that the nutrient premixes are analyzed and a COA is provided by the supplier. In our case, many of the dietary ingredients have USP/NF preparations and the supplier provides COAs with appropriate information.

These two examples from current regulations reveal that testing could and should be less costly and less demanding. The error made is that the testing proposed parallels the drug GMPs rather than the food GMPs.

We respectfully request that the FDA reconsider the proposed regulations and rework them to be in line with the food regulations instead of the drug regulations. That way we can continue to provide safe dietary supplements to our customers and they will not lose their freedom of choice.

Thank you.

Respectfully submitted,



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