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Comments from Small Business Regarding
Proposed Good Manufacturing Practices (GMPs) for Dietary Supplements
Docket #96N - 0417

11.17.99

Greetings,

Herb Pharm is a small manufacturer of herbal liquid extracts, located in a rural portion of southern Oregon. Though small, we are the largest employer in the area and thereby have a significant financial impact on the community. Herb Pharm was founded in 1979 and we pride ourselves on offering what we believe to be the highest quality product of this type available. We mention this because we use superior quality raw materials that are generally not available to the large manufacturer. This includes many botanicals in whole form, a number of which we grow ourselves on our farm. Dealing primarily in small quantities of whole botanicals has a major positive effect on identity testing by greatly reducing the need for high-tech methods.

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Proper identification has always been a critical factor for every botanical used in each batch of product we make. Without proper botanical identification, we would have no credibility with our customers; many of whom are Medical Doctors and other certified health care professionals. As a company, we have over 20 years of experience and expertise in our field, which we apply not only to proper botanical identification but also to every aspect of our manufacturing process. Central for us is the fact that much of our manufacturing is done in extremely small batches, sometimes as little as 5 pounds. We make an extensive line of products, with annual sales at less than 100 single-ounce units. This product diversity is one aspect that differentiates our business from most others and is something that customers count on. In other words, product diversity establishes a niche for our company in the marketplace, distinguishing us and making our business viable.

Low sales volumes for an individual product precludes the ability for that product to financially support multi-method or elaborate testing. This applies not only to high cost chemical testing for identity but to other forms of testing which may become required, such as microbiological and heavy metal screening. Conversely, low sales volumes allow us to pay attention to details such as meticulous cleaning, sorting and inspection of each lot of raw material that we use, in a way that is impossible for large manufacturers.

Herb Pharm supports the establishment of GMPs for our industry as evidenced by the fact that we have begun instituting many aspects of the proposed regulations. We are willing to do anything within reason to provide safe, properly identified products to our customers. One of our major general concerns is that we may be required to go far beyond what is actually needed in order to provide safe products and not be able to bear the subsequent financial burden. Our specific comments, company data and estimated financial impact are included in the following three sections.

I. Please find our specific concerns and comments below, regarding the establishment of GMPs for Dietary Supplements and small business.

Our chief concerns include the following four points:

1.) The potential requirement for microbiological screening of all products. Spot testing has never shown unacceptably high plate counts or any pathogenic organisms. Where as spot testing may be feasible, testing every batch of product presents a major logistical and financial burden.

2.) Any identification testing that may be required beyond the current "at least one test" proposal. Again, we believe that requiring chemical testing for identification of botanicals where low-tech methods are entirely satisfactory is both inappropriate and cost prohibitive.

3.) Additional tests to determine adulteration as defined by FDA. Specifically, full screening for heavy metals for every batch of every product would also be a major logistical and financial burden. We know of no problems resulting from significant accumulation of heavy metals in herbs given the consumption level involved.

4.) Expiration dating. The testing involved to acquire supportive data and rationale is non-existent since we manufacture whole plant extracts. In other words, there is no date at which an extract expires and is no longer an extract. Assigning the entire nature of a botanical to one or even several components would be arbitrary and presumptive at best. Compounding the problem of accurately identifying which of the hundreds of chemical entities in a botanical to quantify is the lack of validated testing methods needed to identify many of these individual chemical components. In addition, the hydro-ethanolic matrix of the majority of our extracts precludes the necessity for accelerated microbiological stability testing.

As this proposed requirement is technologically infeasible, we request that it be completely withdrawn or modified to include only the manufacture date.

II. Please find our detailed company data below.

- Herb Pharm has less than 100 full-time employees
- Our annual gross income is under 10 million dollars.
- We make approximately 250 products, mainly hydro-ethanolic extracts
- Most products are available in 7 sizes.
- Our products are made from over 180 individual botanical raw materials.
- Herb Pharm is a solely owned, private firm.
- We have one certified organic farm and one manufacturing plant.

III. Please find below our estimated personnel and financial impact associated with the establishment of GMPs for Dietary Supplements.

In estimating the cost of establishing the proposed GMPs for dietary supplements, it should be noted that we began this process in May 1999. Since that time, we have hired the approximate equivalent of 1.5 full-time employees (FTEs) to handle GMP implementation.

The only impact we are now considering is the estimated additional burden required to become fully compliant with the proposed GMPs. We estimate that a minimum of 2.0 additional FTEs would be required for us to implement the remaining record keeping and supervision required. One FTE would be at the management level and 1.0 FTE at an hourly worker rate.

Running microbiological testing on our estimated 500 batches per year would add on approximately $20,000 for out-of-house microbiological testing and another $25,000 for aflatoxin testing. Bringing microscopy in house for botanical identification would add approximately $5000 in equipment costs and an additional 0.5 FTE. Chemical identity testing would require 500 TLC tests to be run annually. Performed by an independent lab, these tests would cost between $100,000 to $200,000. Costs for additional adulteration testing and attempted expiration date testing are inestimable.

Thank you for the opportunity to submit comments and your consideration thereof regarding implementation of proposed GMPs for Dietary Supplements on behalf of Small Business.

Sincerely,

Ed Smith

Ed Smith
CEO of Herb Pharm