Herbalist & Alchemist, Inc.

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April 4, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr.
Rm. 1-23
Rockville, MD 20857

To the Food and Drug Administration:

Herbalist & Alchemist, Inc. (the "Company") is a small company under your definition. In fact we are one of a group of hundreds of companies under $5 million in sales and probably should be considered "micro" by your industry definition. We employ 12 people in rural Warren County, New Jersey. Our Company purchases plant material primarily from specialized wild crafters and certified organic herb growers. The businesses of these farmers and gatherers would also be classified as small under your definition.

We appreciate the opportunity to comment on the proposed industry CGMP's. We currently have many of the procedures outlined in place. However, our manufacturing processes and personnel are somewhat different than those in the average large company and therefore our procedures have been tailored to meet our staff's expertise. To adopt these requirements immediately in their entirely would be financially devastating to our company.

We strongly urge you to consider a small company exemption for companies under $5 million in sales. There is precedence for such an exception; DSHEA allows for a small business exception. As long as the products meet the objective of the industry standards which is that they are and will remain (a) safe, not adulterated or misbranded, (b) properly identified and labeled and (c) are of good quality, an exemption makes sense.

With respect to our direct comments on the suggested industry CGMP's:

1) *Personnel (c&d)* Education and training. Most of our manufacturing tasks are taught on-the-job, with appropriate supervision of management. Most of our manufacturing staff have taken or are enrolled in a two year course in herbal studies. Our sanitation control manager is trained in food preparation and management. And we have an experienced nurse as a member of our production staff. Training is tailored to their experience. We do not therefore have uniform documentation with respect to training. We could develop training documentation, but it would take 6 to 12 months to do so.

2) *Plants and Grounds (c-6)* We believe that the same standards that apply to the food industry should apply here.

3) *Sanitation of Buildings and Facilities (h-3)* Air dryers, sanitary towel service or suitable drying devices. We use paper towels which are made from recycled paper which we believe are adequate for hand drying.

4) *Equipment and Utensils (7)* Freezer and cold storage compartments should be fitted with an automatic control for regulating temperature or with an automatic alarm system. We use 2 freezers to prolong the life

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Comments on Section III-Economic Issues:

1) Should there be new CGMP regulations? Should they be mandatory or voluntary?

There are many products grouped under the classification of "Dietary Supplements". Some are highly processed isolated chemical compounds such as melatonin, amino acids or phytochemicals and they should require CGMP's. However, crude botanical extracts have been made safely and effectively for thousands of years. Among the manufacturers of these products, there are many small companies and we believe that a small company exemption should apply. In addition, we do not believe the same level of CGMP'S should be required for this product. We believe that these products must be properly identified botanically, labeled accurately and be produced in a facility that meets the state health codes for food processing.

These types of botanical extracts have had hundreds of years of safe and effective use in traditional and ethnic communities. Depriving traditional communities such as the Asian-American, Hispanic, African American, Jewish and Native American of products that have had a long history of use in their cultural and religious beliefs threatens their basic human rights.

We therefore believe that CGMP's should be voluntary for companies under $5 million in sales that are making traditional botanical products.

2) If the CGMP's are mandatory how long would they take to implement.

Record-keeping We believe that full implementation of all record-keeping procedures and written accounts of methodologies could take up to 1-2 years to implement.

Mircrobiological and Aflatoxin testing We are working with Rutgers University - Cook College, the agricultural college, to develop low cost testing procedures, but it may take a number of years to develop and implement these procedures.

3) Cost of Implementation - CGMP's

Record-keeping We do not believe the cost of increased record keeping would be too substantial, but it will take time to implement.

Mircrobiological and Aflatoxin testing We believe that the implementation of these procedures could be prohibitive and potentially cause us to close our business.

Comments on Section IV-Additional Questions:

1) Need to develop defect action levels? Our Company purchases plant material primarily from specialized wild crafters and certified organic herb farmers. On receipt of our raw herbs, which we receive in their whole state, we thoroughly inspect all plant material. We remove any foreign matter and discard any inferior plant material. We operate in an industry that uses plant material. Plants by their very nature are living organisms. To subject the plants to high heat or to irradiate the plants would degrade the product to a useless level; spraying with ethyl di-bromide would be toxic and potentially carcinogenic. We believe that by working directly with reputable and knowledgeable suppliers, we have addressed this issue.

2) Appropriate testing requirements to provide positive identification of dietary ingredients, particularly plant materials used in dietary supplements. We believe the industry guidelines in the CGMP's address this issue adequately. Quoting from that section: "Such tests may include any appropriate test with sufficient specificity to determine identity, including chemical and laboratory tests, gross organoleptic analysis, microscopic identification, or analysis of constituent markers." With respect to our

of certain dried herbs. We believe the manufacturers' regular settings on our freezers are sufficient for this purpose because if the freezers malfunction the herbs will not spoil as they are already dried. We do not believe there is a need for additional warning devices.

5) *Equipment and Utensils (b-11)* Written record of major equipment cleaning and use that show the date, product and lot number of each batch processed. Our equipment is cleaned after each use. This can often be several times in one day. We maintain detailed production records of batch and lot processing and financial records detailing equipment maintenance. We could adapt our production records to make note of which machines were used and start additional logs to reflect the records suggested, but we believe this record keeping would be onerous compared to the benefits it would provide.

6) *Quality Control and Laboratory Operations (a-3)* Quality control unit responsibilities and procedures shall be established in writing and followed. Three senior officers of the Company and our lab managers comprise our quality control group. Certain members of the group review the production records weekly. We do not have a formal written procedure. We could develop written documentation, but it would take 6 to 12 months to do so.

7) *Expiration dating* We currently use our industry's generally accepted expiration dates. We also test our products organoleptically. Stability studies would be time consuming and financially burdensome.

8) *Production and Process Controls (a-2vii)* Description of the product containers, closures, and other packaging materials, including positive identification of all labeling used. We need clarification here. We use the same type of container for each extract and labels are made on a labeling machine. All bottles are secured with tamper proof seals.

9) *Production and Process Controls (c-5)* Written procedures shall be established and followed describing the receipt, identification, examination, handling, sampling, testing and approval or rejection of raw materials. We have a consistent method of performing these procedures. If procedures must be written, it would take 6 to 12 months to do so.

10) *Production and Process Controls (c-7), (d-2)* Raw Materials

c-)
i) We spend a substantial amount of time examining and removing any foreign matter or inferior plant material from that which we use in our preparations. We believe this procedure complies with applicable standards.

ii&iii) We are operating in an industry that uses plant material. Plants by their very nature are living organisms. We have never had a problem with this issue in our 15 years of operation. Our Company purchases plant material primarily from specialized wild crafters and certified organic herb growers. We believe doing extensive microbiological testing would be prohibitively expensive.

iv) We commend the industry for including organoleptic testing in this section. We note that we receive most of our plant material whole (not in powder or cut/sifted). We believe that visual identification by trained ethnobotanists or herbalists is also a testing method that should be added.

c-i-v, d-2) We would find microbiological and aflatoxin testing to be prohibitively expensive. The high quality extract makers in the herb industry have been working for over 20 years without any recorded incidence of microbiological or aflatoxin contamination.

11) *Production and Process Controls(d-2)* We would need clarification on this section.

12) *Production and Process Controls(d-2)* Written procedures are partially done for this procedure. Detailed documentation would take 6 to 12 months to implement.

Company, our laboratory and quality control personnel have had extensive experience and training in herbal products, botany, pharmacognosy and cultivation of botanicals. We are satisfied that organoleptic testing is sufficient for product identification. As a small company we work with a great number of small lots of material. We inspect each lot thoroughly and remove any foreign plant material. Microscopic identification is used if there are any unresolved questions from the organoleptic tests. We have an in-house pharmacognosy reference library. Failing these methods of identification, we have a close relationship with the agricultural land grant university, Cook College at Rutgers University. We would work with their experts to ascertain positive identification.

3) Certifying that a dietary ingredient is not contaminated with filth. We believe that dietary ingredients should meet the same standards as food. We work primarily with certified organic growers, therefore we are reasonably certain that there are no pesticide residues in our product. As any food manufacturer we accept their assurance that their products do not contain filth or foreign matter that would adulterate the product. We inspect each lot thoroughly and remove any foreign plant material or bugs. Any plant material that is compromised is discarded. Dried material is stored in insect/rodent proof containers. We actively maintain an effective pest control program.

4) Should the FDA establish procedures to document the CGMP's. We believe that the CGMP's are helpful guidelines for manufacturing companies. We believe that each company must adapt these standards for their own specific situation. We believe that each company should establish appropriate practices to ensure the goals of producing high quality products for consumers.

5) CGMP's report injuries and evaluated by a medical doctor to protect the public health. A number of years ago the American Herbal Products Association established a hotline for reporting any problems with the herb, chaparral. This hotline is still active and continues to be effective. The American Herbal Products Association is also considering establishing a more general hotline for all herbal products. We believe this action will be effective in addressing this question. Our own experience in the 15 years we have been in business, has been that there have been a few isolated reports, none of which have been unresolved.

6) Should CGMP's require that manufacturers establish procedures to identify, evaluate and respond to potential safety concerns with dietary ingredients? The American Herbal Products Association has developed a Botanical Safety Index for this purpose and has submitted it to the FDA. The Botanical Safety Index was developed and reviewed by some of the most respected herbalists and educators in the herbal industry. Our own herbalist, David Winston (Herbalist AHG and Ethnobotanist), was among the reviewers. We believe this document addresses this issue adequately and we are implementing its suggested label changes.

7) Specific controls for computer controlled or assisted operations...how best to ensure that the software programs and equipment used to direct and monitor the manufacturing process are properly designed, tested, validated and monitored. We believe that establishing a quality review group that reviews weekly production records and having a knowledgeable production staff are sufficient to insure that the manufacturing process is correct. Our computer system is a record keeping system. We have a series of reviews of data and procedures in order to maintain its accuracy. Our processes are overseen by trained people at every step of the processing. We also have hand written records of inputs for checking and comparison.

8) We are making a thorough review of the HACCP principles and are discussing their applicability with our colleagues in the industry. At this point we refer you to our answer outlined in #9 below.

9) CGMP's adequate for the broad spectrum of firms in the dietary supplements industry? We cannot speak for all the companies in this industry, but with respect to our Company, with the modifications outlined above, we believe the industry proposed CGMP's are adequate for our operation.

Thank you for the opportunity to respond to the issues you have outlined. Please do not overlook the needs of the small businesses in our industry. Our Company has grown between 20-40% over the last few years. We now employ 12 people, and will be hiring at least 1-2 more people this year. Our plant material purchases support many small farmers in our area, where farming is being lost as a way of life and farmers are under severe pressure to sell their land for housing development. We are one of a group of hundreds of companies under $5 million in sales and probably would be considered "micro" by your industry definition. We strongly urge you to consider a small company exemption for companies under $5 million in sales. There is precedence for such an exception; DSHEA allows for a small business exception. As long as the products meet the objective of the industry standards which is that they are and will remain (a) safe, not adulterated or misbranded, (b) properly identified and labeled and (c) are of good quality, an exemption makes sense.

We believe that many of the issues with respect to cleanliness are covered by the state boards of health regulations, which we follow. We have been inspected. With the type of products we are manufacturing, we do not believe we should be subjected to more stringent standards than the food processing companies.

One of our colleagues who alerted us to your call for comments on these subjects noted that "similar regulations in Australia put out of business any company doing less than $1 million/year." One of our officers recently attended a conference on sustainable development in Australia and met with some herb processors. This observation was true. Let's prevent this from happening to small, responsible, ethical herbal entrepreneurs, some of whom make the finest quality herbal products produced in the United States.

Please keep us informed of any public hearings on this matter. We will send a representative from our company to make our views known verbally.

Sincerely,

The employees at Veriditas Botanicals

Melissa Ferris