GAIA HERBS

Manufacturer of Premium Botanical Extracts and Liquid Phyto-Caps™

21 May 2003

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

Dear Sir or Madam:

Following are comments that Gaia Herbs, Inc. would like to make regarding the newly promulgated Dietary Supplement cGMPs published as a final proposal on 13 March 2003. We are submitting these comments for your consideration prior to the original deadline of 11 June 2003 as recommendations for clarification or changes to the proposed rules.

1. **Subpart B--Personnel:**
   - Section 111.12 Personnel and 111.13 Supervision. These sections need clarification as to what type of training and experience is required. These sections need more information in the way of guidance as to what is expected in the industry to confirm that "qualified" personnel requirements have been met.

2. **Subpart C--Physical Plant:**
   - Language for the plant and grounds similar to that found in the Food cGMPs under Subpart B--Buildings and Facilities, 110.20 Plant and Grounds, is needed explaining these requirements. This language is helpful in training staff and explaining to plant maintenance personnel what is required and why, for example, proper draining of areas is needed to protect against providing breeding places for pests, etc., etc.

3. **Subpart D--Equipment and Utensils**:
   - Section 111.25 (e) 3 states that if you use wet processing during manufacturing, you must clean and sanitize all contact surfaces. The definition for "Sanitize" in Subpart A Section 111.3 states in part that you must adequately treat equipment, containers, utensils, or any other dietary product contact surfaces by applying cumulative heat or chemicals to yield a reduction of 5 logs, which is equal to a 99.999 percent reduction, of representative disease microorganisms of public health significance. This requirement in our opinion misdirects the intent of the law to an overly impractical means, not of achieving sanitized conditions, but of

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consistently validating them. We would recommend that language be substituted to state that equipment, utensils, etc., should be cleaned and sanitized in a manner that keeps microorganisms and other adulterants from contaminating all components, ingredients, in-process and finished product. In this scenario, the microbial and analytical test results of product produced on a facility's equipment, coupled with random testing of equipment and utensil final rinse water, would provide sufficient and continuous evidence of a proper and effective cleaning and sanitizing plan. The proposed language denotes the same "validation methodology" that is found in Drug cGMPs, 21 CFR 211. Since the intent of DSHEA legislation and subsequent regulatory concern has been to base Dietary Supplement cGMP's on Food, and not Drug, standards, we believe that placing the empirical burden of proof of purity on the product, rather than on product contact surfaces, delivers safety to consumers in a feasible and proper manner.

4. **Subpart E--Production and Process Controls**
   - 111.35 g (1) states that you must test each *finished* (as opposed to raw material or component) batch of the dietary ingredient or dietary supplement before releasing for distribution, as established under section (e), *unless* no scientifically valid analytical method is available. This implies, for example, that each *raw* ingredient or *in-process* component in an herbal formula would need to be tested *only* if no scientifically valid method existed for testing the *finished* product. However, in many cases involving blended herbal supplements, and particularly with liquid blends, it is not a lack of scientifically valid test methods that compels testing of individual components or in-process product, it is instead far more *practical* and *scientifically valid* to do so. We believe, therefore, that this language needs to be modified to allow for other strategies to be used when they can be proven better and more scientifically sound. For example, it is more relevant and valid to our finished product quality, and to the single ingredient "mg per dose" amounts specified on our blended product labels, that we comprehensively test in-process products while they are still in a single herb or component form. We certainly *could* test the final product blend for each component's concentration in solution, but doing so would present an impractical and illogical burden on our laboratory and, in the event of product non-compliance, effectively prevent adequate recovery or reprocessing steps to be made. Instead, comprehensive tests of each component immediately *prior* to final blending makes more sense and yields more accurate scientific data. Final product testing criteria should specifically allow *a combination* of *final* product test data, such as microbial data, heavy metal data, and standardized marker data, *and* analytical data on the *sub-* and *in-process* components that made up the final product, when the case for such a testing method is valid. Accurate batch records would confirm the amounts of the individual ingredients that were added and would therefore confirm and authenticate the final product's quality, purity, consistency, and strength. We request clarification from FDA on this matter so that an absence of valid scientific finished product test methods is not the only allowable trigger for sub-component testing.

- 111.35 (l). We request clarification on whether gross organoleptic analysis alone can be an adequate and valid test methodology for releasing finished products. If so, we propose clarifying the language of this section to say that gross organoleptic analysis *cannot* substitute for microbial and heavy metals analysis, and can only serve as an indicator of chemical identity and strength when no competent and scientifically-valid testing methods can be proven by the manufacturer to exist. Otherwise, TLC, HPLC, GC-MASS, etc., *must* be used in conjunction with gross organoleptic analysis to assure the quality, purity, strength, identity, and consistency of every batch of every finished product.
- 11.50 (c) 2. We request clarification on whether the persons responsible for batch production and/or validation steps be identified specifically in batch production records (e.g., by name), or whether they may be identified more generally by position description or departmental authorization.

5. **General:**
   - **Written Procedure Requirements**. We recommend that the new regulations be made closer to the original proposed dietary supplement regulations and to current FDA Food regulations in regard to the clarity of the law's actual procedural requirements. We believe that it would be much clearer and less confusing to all parties if specific written procedures were listed as required. Requiring fewer procedures, as the proposed regulations seem to do, tends to make the implementation of a cGMP system more, not less, confusing. We prefer a type of guidance in which all companies would know exactly what is expected of them procedurally. Knowing where, specifically, in the regulations an item is required, via a "shall" statement for example, is much better than being left without clear mandates. For example, the ISO quality management standards (recently changed to ANSI/ISO/ASQ Q9001-2000), despite their more generalized application across all industries, nevertheless provide a coherent and systematic framework that clearly distinguishes "guidances" from "requirements". We recommend that FDA clearly distinguish guidances from requirements using a clear, unambiguous citation methodology and a presentation format that facilitates real compliance with the law.
   - **Voluntary Compliance Inspections**. Gaia Herbs recommends that during the implementation period for the new regulations, a voluntary compliance inspection program be implemented. We advocate using the same type of program adopted by OSHA under 29 CFR regulations as a model for this type of program. Under this program, when a company believed that they were fully compliant under the new regulations, they could contact FDA and arrange for an inspection. The inspection would be done without penalty or cost to the company involved unless a serious violation was noted. It is believed that these inspections and the information learned through these inspections would be of great value to this industry. It would help both FDA and companies in the dietary supplement industry develop a helpful trust factor and aid both in achieving faster overall compliance in the industry. We also believe that voluntary compliance inspections would encourage companies to be more pro-active in implementing cGMPs and

to feel freer in contacting the FDA for help in the various phases of implementation.

- **Signatures**. Will FDA allow electronic signatures on batch production records, laboratory test results, and quality control unit documentation? Many companies have fully computerized, automated production and quality control management systems that utilize password-protected (or otherwise secure) means of entering data at key quality control steps. We request clarification on this general point and would strongly recommend that FDA allow electronic signatures utilized within FDA- approved production process management software.

We hereby submit these comments and believe that they will help in the overall objective of enabling both the Dietary Supplement industry and FDA to assure consumers that these products are pure, safe, and effective.

Yours Respectfully,

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Regulatory Compliance Officer

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