May 19, 1997

Re: 21 CFR, Ch. 1
Current Good Manufacturing Practice in Manufacturing, Packing, or Holding
Dietary Supplements; Proposed Rule, dated February 6, 1997

Docket No. 95N-0417; Extended comment deadline: June 7, 1997

Department of Health and Human Services
Food and Drug Administration
Docket Management Branch (HFA-305),
Food and Drug Administration
12420 Parklawn Dr. Rm. 1-23
Rockville, MD 20857

Dear U.S. Food and Drug Administration,

Prairie Smoke Corporation, dba Herbs for Kids, Inc., respectfully submits the comments below regarding the proposed Current Good Manufacturing Practice (CGMPs) rules. In the Advance Notice of Proposed Rule making, the FDA specifically asks for comments from smaller herbal manufacturing establishments such as our own.

We do entirely support the implementation of modified food GMPs into the dietary supplement industry so that clean, unadulterated products are accurately labeled and safely available to the public. We remain comfortable with the final clarification by the Dietary Supplement Health and Education Act of 1994 that requires dietary supplement GMPs be modeled after those for food.

Herbs for Kids™ has finished six successful years of manufacturing liquid herbal extracts. Being one of the smaller member companies (less than 30 employees), our regular participation in the American Herbal Products Association has assisted us in creating and employing the vast majority of record-keeping and sanitary procedures outlined in the CGMPs. However, there are several areas that we find in need of comment. Specific remarks follow below.

Page 5705, Sec. 11
CGMP wording: " Written procedures shall be established...that appropriate tests, and/or examinations to be conducted that may be necessary to assure the purity, composition, and quality of the finished product."

Comment: Complying to food-based DALs should be a shared responsibility between farmer/broker and wholesale herb purchaser/manufacturer. Manufacturers alone

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96N-0417

Page 5707, Summary and Request for Comments

Comment 1
Re: Is there a need to develop specific defect action levels (DALs) for dietary ingredients?

Comment: While we believe that food ingredient DALs are sufficient for public safety, we realize that separate dietary supplement DALs could provide more meaningful information. It is our understanding that DALs for the food and spice industry were created in alliance with food manufacturers, and suggest that any future changes be made in this fashion, apart from this CGMP discussion.

Comment 2

Re: CGMP wording: " ...The use of a botanical in a dietary supplement may result in a much greater exposure to the botanical ingredient for consumers because the dietary supplement will be consumed in greater amounts than if the ingredient was in a food as a spice or flavoring agent."

Comment: We strongly disagree with this statement. Foods are not only consumed in much greater quantities; foods are also consumed daily. Dietary supplements are used supplementary to the diet, generally for short periods of time in small amounts. The DSHEA specifically states that dietary supplements are "safe within a broad range of intake" and "safety problems with the supplements are relatively rare". Historical data fully supports the safety of the extensive majority of herbal dietary supplements.

Comment 3

Re: CGMP wording: " FDA requests comments on appropriate testing requirements to provide positive identification of dietary ingredients, particularly plant materials, used in dietary supplements".

Comment: Because Herbs for Kids purchases whole plants and roots, identifies and subsequently manufactures our own products, we find that a comprehensive organoleptic testing and botanical identity program is entirely valid for our uses. Specimens are retained. Requirement of thin layered chromatography (TLC), high performance liquid chromatography (HPLC), gas chromatography, or mass spectrum analysis for identification, rather than safety, purposes would be entirely superfluous in our type of manufacturing operation, and would incur enormous additional and unnecessary costs that could potentially threaten our company's financial viability. Again, this comment is specific to our own botanical product manufacturing operation, and should not necessarily be construed to include other synthesized or powdered dietary supplement ingredients.

should not bear entire responsibility for natural and unavoidable defects in products intended for human use.

Page 5707, Economic issues
CGMP wording: "FDA requests comment on...how costly it would be to bring those practices into conformity..."

Comment: As stated earlier, Herbs for Kids, Inc., currently follows the vast majority of documentation and cleanliness guidelines outlined in the CGMPs. We estimate that creation of Standard Operating Procedures and Good Manufacturing Practices by other small manufacturers should be budgeted to include a minimum annual expense of approximately: $31,600, broken down as:

.5 FTE salary for Production Manager to create and enforce GMPs:	$ 20000
Annual cost for two employees to spend 1 hour each more per day to comply with GMPs and related record-keeping:	$ 5500
Minimum out-sourced lab testing program:	$ 3600
Additional estimated GMP-related operating expenses:	$ 2500

Again, these are minimum levels of expense. Should a smaller-scale herbal product manufacturer be operating at a 10% net profit margin, we can draw a theoretical conclusion that no less than $360,000 extra sales per annum are required to make the implementation of minimum GMPs cost-effective. This could be financially devastating for some of the smaller, yet high quality, members of the industry.

Page 5707, Economic issues
Re: Definition of small and large businesses

Comment: A quick look at members list of the American Herbal Products Association (AHPA) (the only trade organization in existence for natural products industry manufacturers and interested parties) would lead one to believe that many of the industry members are much smaller than SBA-defined 'small' businesses as noted in the proposed CGMPs. Many of the member companies employ less than 50 workers, and do significantly less than $10 million in sales. It is our conjecture that dietary supplement manufacturers showing less than $1 million in sales and/or those business with less than 30 FTE (full time) workers would suffer financial hardship, and perhaps would be forced to cease operations due to the CGMPs. While no compromise in safety standards should be allowed, there must be provisions for smaller companies to endeavor to meet CGMP standards over a set period of time to make the increase in operational expenses viable. However, Herbs for Kids is not in favor of a complete exemption for any size company.

Comment 4

Re: CGMP wording: "The agency asks for comments on whether dietary supplement CGMPs should require that reports of injuries or illnesses...be evaluated by competent medical authorities."

Comment:
Again, we must comment that according to DSHEA, by law dietary supplements must be evaluated in a fashion consistent with evaluations already in place for food products. We believe that the CGMP regulations for food are entirely adequate to protect the public's health.

Should a group of 'competent medical authorities' be formed to evaluate herbal products, Herbs for Kids feels it must be noted that any group would need to be comprised of not only Medical Doctors, pharmacists, toxicologists, dietitians and other medical personnel; in addition, highly trained clinical herbalists must also be included in this proposed group. It is our understanding that few, if any, medical or pharmacy schools in the nation provide an adequate curriculum in dietary supplements and/or herbal medicine. To ask other medical experts to comment on areas they are clinically untrained in would be ill-advised.

Page 5708, Summary and Request for Comments
Re: Section 8: "The agency asks for comments on whether certain, or all, of the requirements for manufacturing and handling dietary ingredients....may be more effectively addressed by... Hazard Analysis and Critical Control Points (HACCP)..."

Comment: After great discussion with industry members, we have concluded that dietary supplement HACCPs are inappropriate and unwieldy for the dietary supplement industry. If and when HACCPs are put into place for the food industry (beyond the limited food HACCPs currently in place for seafood items) this discussion could be reopened.

Re: Section 9: "The agency asks for comments on whether broad CGMP regulations will be adequate..."

Comment: It is most certainly worthwhile to explore the broad variations between those manufacturing operations dealing specifically in botanical products, as compared to those whose operations are solely involved in the manufacture of dietary supplements made from synthesized ingredients. While herbal ingredients generally have long histories of food use and historical safety parameters, many vitamin, mineral, amino acid, glandular and other fractionated supplements are relatively new for human consumption. To create identical manufacturing guidelines for these vastly dissimilar operations and consumer usage patterns has the potential to create overly burdensome guidelines for the botanical manufacturers, and could potentially

overlook important considerations for the vitamin/supplement industry.

In summary, Herbs for Kids, Inc. is generally pleased with many of the parameters suggested by the CGMPs. We ask for strict adherence to the Dietary Supplements Health and Education Act of 1994 that CGMPs be modeled after CGMP regulations for foods. We ask the agency to consider the costs of implementing proposed guidelines upon the smallest manufacturers and to consider the broad variations in manufacturing standards between the vitamin and herbal manufacturing segments of the industry. We suggest further discussion regarding the creation of DALs and HACCPs be reviewed as separate from the initiation of dietary supplement CGMPs.

Thank you for the opportunity to comment.

Sincerely,

Susan P. Mavor
President
Herbs for Kids, Inc.

Herbs for Kids

Hard copy enclosed SPM 6/6

FAXed 6/6/97

97 JUN -9 P1:33

June 6, 1997

PLEASE DELIVER IMMEDIATELY TO:

Dockets Management Branch, Food and Drug Administration

(Department of Health and Human Services
Food and Drug Administration
Docket Management Branch (HFA-305),
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Re: 21 CFR, Ch. 1
Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements; Proposed Rules

from: Susan P. Mavor

Number of pages including this page: 6

Please contact this office immediately if all pages have not been received.

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97 JUN -6 P4:55

June 6, 1997

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Dockets Management Branch, Food and Drug Administration

(Department of Health and Human Services
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Re: ANPR on CGMPs for Dietary Supplements industry

From: Susan P. Mavor

6/9/97

6 ~~*~~ pages, including cover

Message: This is a re-fax of our fax on Friday, June 6 as requested by Jenny Butler in your office today. Evidently, Friday's fax did not transmit clearly. Hard copy was mailed to your office on Friday, June 6 as well.

Please call immediately if all pages do not transmit.

SPM

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