DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville MD 20857

HFA-305

October 28, 1997

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David N. Wilson
President
Folexco Flavor Ingredients
150 Domorah Drive
Montgomeryville, Pennsylvania 18936

Dear Mr. Wilson:

This is in response to your June 6, 1997, letter to Dr. Michael Friedman concerning the manufacture of dietary supplements. I apologize for the delay in responding.

In your letter you state that reputable suppliers welcome a GMP protocol for the industry, botanical standards, truth in labeling, and valid claims or more focused disclaimers for the consuming public.

The Food and Drug Administration (FDA) recognizes that the use of herbal ingredients in dietary supplements creates a number of challenges in regard to developing a regulatory framework to ensure that they are safe and claims made for them are supported by sound science. We believe that requirements governing the manufacture of herbal dietary supplements, including the evaluation of potential safety concerns, could be effectively addressed by establishing GMPs for dietary supplements. Therefore, the agency announced, in a February 6, 1997, advance notice of proposed rulemaking (ANPR), that it is considering whether to institute rulemaking to develop regulations that prescribe current GMPs for dietary supplements and dietary supplement ingredients. Two of the issues that will be addressed by such rulemaking are whether herbal ingredients may need a separate regulatory framework and what steps may be necessary on the part of manufacturers to ensure that their products are safe.

We have submitted your letter to the FDA Dockets Management Branch for filing in the public docket. Your letter, along with correspondence and comments from members of the public, will be considered as the agency develops proposed regulations for establishing GMPs for dietary supplements.

Thank you for your interest in this important issue.

Sincerely yours,

Vicky Bee Wolfhard
FDA Executive Secretariat

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June 6, 1997

Michael A. Friedman, M.D.
Lead Deputy Commissioner
Food and Drug Administration
5600 Fisher Lane
Rockville, Maryland 20857

Dear Dr. Friedman:

I have just finished reading an outline of the Ephedrine Proposal and finally we are beginning to see some logical controls in the wide area commonly known as Nutraceuticals and Cosemeceuticals.

I have been in the botanical flavor ingredients industry for over twenty (20) years and Folexco has always maintained food grade GMP, produced botanicals with low micro, good quality, and always advised the customer exactly what they were getting via HPLC, TLC, and our internal and ISO 9002 Certification.

During the past two years we have been requested to begin producing large volumes of product for the supplements industry and after visiting the retail vendors, franchises, and some of the other manufacturing and technical support groups, I am begging for an external control base to bring some functional sanity to this industry. While the AHPA, American Botanical Council, and Botanical Research Council are trying to develop an internal program of analysis and control, it will never happen as long as the supply chain and production infrastucture is not subject to inspection and review by a licensing agency.

I have been in powder grinding and blending plants that have no infestation control, no rodent control, little or no micro testing, no foreign matter specifications, no maintenance programs, little or no training programs and would never be permited to sell finished products into the food industry per se. These producers and vendors are bottling products for some of the major chains and as long as the customer and the consumer continue to pay for adulterated and poor quality product with no external control, I do not see a change developing no matter how hard the supplements industry is trying to police itself. The supply base is too diverse with too many "Cowboys" and eclectic thinkers who will always want to work outside the scope of a structure.

The reputable suppliers welcome a GMP protocol for the industry, botanical standards, truth in labeling, and valid claims or more focused disclaimers for the consuming public. If I can support your activities in any way, please do not hesitate to call me at the Folexco Office in Montgomeryville, Pa.

In response to the issue on Ephedrine, we have now been flooded with calls to replace Ephedrine with Citrus Aranteum (Synephrine) and Caffeine. This industry alway amazes me in the the methods of substitution and if as much time was spent on ethical protocols as is being spend on insuring that the FDA, NIH, HHS, CDC, et. al., were kept away from the industry, we would all be better off.

Sincerely,

David N. Wilson
President
Folexco Flavor Ingredients

FOLEXCO FLAVOR INGREDIENTS F.F.I.

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