

FOLEXCO

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June 5th, 1997

Food and Drug Administration
Dockets Management Branch
HFA-305
Room #1-23
12420 Parklawn Drive
Rockville, Maryland 20857
RE-Docket Number 96N-0417
GMPs for Dietary Supplements

Gentlemen:

Folexco Flavor Ingredients has been involved in the flavor intermediate and botanical extract industry for approximately ten (10) years. During the ten years we have developed processes and procedures that are Food GMP based and also adhere to the same procedures when producing both powdered botanicals and yield or standardized extracts for use in the food supplement industry.

As a supplier to both the food and supplements industry Folexco has had the opportunity to test, measure, analyze, match and comment on the products of other members of the supplement industry and unfortunately, the results are not good or as the industry in general is promoting.

The industry is in dire need of a GMP base and all of quality protocols that are involved in its basic standards. I have seen plants producing finished products for the industry and selling in branded franchises that would never be allowed in a food system or even be allowed in most food grade facilities. While most of the industry states a "Do no harm" philosophy, I believe that the general public is being misled related to both functionality and quality by most of the producers in the industry. The general condition of most of the facilities I have visited are quite disturbing related to cleanliness, rodent control, infestation, and general maintenance.

Adulteration, substitution, down-blending, and mis-labeling/mis-advertising are general practices for most of the industry and even though the American Botanical Council, AHPA, Botanical Research Council, et. al. are trying, there are just too many producers who will put anything in a bottle as long as the supplier is willing to take advantage of the lack of testing in the industry and substitute or adulterate a product for a pricing motive.

A member of the worldwide A. M. Todd Group of Companies

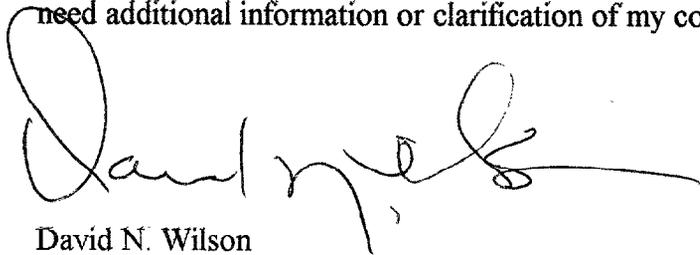
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96N-0417

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This industry needs help and legitimization and as long as the industry is as diverse as it is, the required internal policing will not occur. Please do not hesitate to contact me if you need additional information or clarification of my comments.

A handwritten signature in black ink, appearing to read "David N. Wilson". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

David N. Wilson
President
Folexco Flavor Ingredients