



# SCIENTIFIC BOTANICALS COMPANY

P. O. BOX 31131

SEATTLE, WASHINGTON 98103-1131

(206) 527-5521

June 3, 2004

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Food and Drug Administration  
Attn: Lisa M. Althar, Compliance Officer  
22201 23<sup>rd</sup> Drive S.E.  
Bothell, WA 98021-4421  
Ref: Warning Letter SEA 04-31

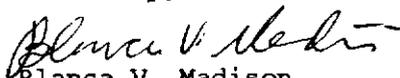
Dear Ms. Althar:

This letter is written in response to Warning Letter SEA 04-31 from Mr. Charles Breen, District Director, dated May 21, 2004, which was the product of several inspections and analysis on product material and labeling. In above mentioned letter the following concerns were addressed:

1. Analysis showed that our product Hydroxy-Folate was in violation of Sections 402(b)(1) and 403(a)(1) of the Federal Food, Drug and Cosmetic Act. Since our meeting with agent Katie Alford on February 2, 2004 we have discontinued sales of said product, as per suggestion of Ms. Alford. During Hydroxy-Folate cessation of sales we have been working to revise and improve the formulation in hopes of resuming sales of a product void of violations.
2. It was also stated that products Hydroxy-Folate, Deglycyrrhizinated Licorice D.G.L. and Quercetin were misbranded under Section 43(i)(1) and 403(s)(2)(B) of the Act because of the fact that the term "dietary supplement" or variation of that term was not on their labels. After becoming aware of these violations we have revised the above mentioned labels as well as the labels of our entire line of products in accommodation of this requirement and any other requirements applicable.
3. In regards to the statement that Hydroxy-Folate, Deglycyrrhizinated Licorice D.G.L. and Quercetin were additionally misbranded under Section 403(q)(5)(F) of the Act because of the failure of their labels to bear a "Supplement Facts" panel, required under 21 CFR 101.36. Our products in fact are exempt from this regulation under 21 CFR 101.9(j)(1), 21 CFR 101.9(j)(18) and 21 CFR 101.36(h). We submitted our exemption notification on 1/28/04, and believe that we are in complete concordance in this area.

Hopefully we have provided you with adequate information in response to your concerns, please contact us with any input.

Sincerely,

  
Blanca V. Madison  
CEO

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- Enclosure: 1. Copy of revised labels of DGL and Quercetin.  
2. Copy of the Small Business Food Labeling Exemption Notice.