



Food and Drug Administration
Center for Biologics Evaluation
and Research
1401 Rockville Pike
Rockville MD 20852-1448

April 2, 2003

CBER-03-007

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bill Gray, M.D.
Bill Gray Medical Corporation
20600 B Lomita Avenue
Saratoga, CA 95070

Dear Dr. Gray:

The Food and Drug Administration (FDA) has reviewed your website at Internet address: <http://www.billgray.net> and has determined that your Dr. Gray's Smallpox Shield (Homeopathic) preparation of Variolinum administered as sugar pellets saturated with remedy is a biologic, as defined in section 351(l) of the Public Health Service Act (PHS Act) [42 USC 262] and a drug under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)] because it is intended for use in the prevention of disease. Variolinum is not recognized by the Homeopathic Pharmacopoeia of the United States. On your website, this product is purported to prevent smallpox and is compared extensively to the vaccine for smallpox.

Examples of the claims observed on your website include: "...prevents smallpox despite direct exposure;" "...proven in smallpox epidemics throughout the world;" "...its safety and effectiveness are unassailable...;" "...effective in preventing side effects of the vaccine;" "There is no danger in taking it more often than recommended;" "...it is of no danger to family members in any way;" "...manufactured, packaged, and shipped by Hahnemann Laboratories...;" "Completely safe by FDA;" "This laboratory specializes in homeopathic products and is monitored routinely by the FDA...;" "...effective and safe in preventing side-effects of vaccination...;" "...effective and safe in preventing smallpox, even in caretakers with close contact;" "...is safe in children, pregnant women, people with history of eczema, and people with AIDS or who have been immunosuppressed;" "Because it is preventive and completely safe, there is no need for a usual doctor's visit...;" "...not only protects efficiently against smallpox itself but also to effects of cowpox vaccination;" "In addition to preventing smallpox, it validates immunity by creating non-reactivity to vaccination...in both human and

animal models;" and "...it is nontoxic - completely effective against Variola major and against cowpox reaction."

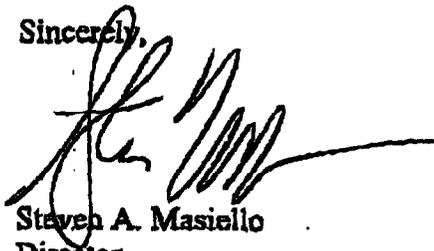
Please be advised that in order to introduce or deliver for introduction a biologic into interstate commerce, a valid biologics license must be in effect. Such licenses are issued only after a showing of safety and efficacy for the product's intended use. While in the development stage, biologic products may be distributed for clinical use in humans only if the sponsor has on file an accepted investigational new drug application as specified by the regulations (21 CFR Part 312). Exemptions from the requirements of demonstrated safety and efficacy for drug products are granted under section 505 of the FD&C Act. Based on a review of our files, FDA has no information that your product is the subject of an approved biologics license application (BLA) or investigational new drug application (IND). Therefore, your shipments of product for which a valid license or IND is not in effect and which are at variance with the provisions of 21 CFR Part 312, represent violations of the PHS Act and the FD&C Act (the Acts) and may result in the Agency seeking such relief as provided by law.

It appears that your product is for sale to U.S. citizens because the "checkout page" of your website provides specific shipping charges for U.S. shipping. Your website also states that Dr. Gray's Smallpox Shield (Homocopathic) "remedy is available only by prescription," and that this prescription is provided through your website for a fee. Once the prescription is obtained through your website, the consumer may purchase your remedy directly from you.

This letter is not intended to be an all-inclusive review of your website and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Acts and their implementing regulations. You should take prompt action to correct the violations noted above. Failure to promptly correct these violations may result in regulatory action such as seizure and/or injunction without further notice.

Please notify this office in writing within 15 working days of receipt of this letter of any steps you have taken or will take to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200 N, Rockville, Maryland 20852-1448, Attention Mr. Steven Masiello, Director, Office of Compliance and Biologics Quality.

Sincerely,



Steven A. Masiello
Director

Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research