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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

CBER-04-004

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

January 16, 2004

WARNING LETTER

USPS

Biologicalmiracle.com
PO Box 726
London, England EC1V 7QQ
United Kingdom

To Whom It May Concern:

The Food and Drug Administration (FDA) has reviewed your website at Internet address: http://www.biologicalmiracle.com and has determined that your product "the Antidote," which is purported to be an "Anti-Microbial Peptide" derived from the blood of crocodiles, is being promoted for conditions that cause it to be a drug under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)] and a biological product, as defined in section 351(i) of the Public Health Service Act (PHS Act) [42 USC 262].

"The Antidote" is considered to be a drug because the therapeutic claims, as shown on your website, establish its intended use as a drug. In describing "the Antidote," your website states, among other things, that: " It will fight and protect your body from all virus and bacteria activated infections"; "The miracle healing powers of the Antidote can now be used to fight all known human viruses and bacteria. The common cold is a thing of the past, even serious infectious diseases such as Cancer, AIDS, SARS and many other life threatening diseases can be helped by the power of the Antidote"; and "Whether you have the common cold, a terminal illness, or you just want to protect your body from viruses and bacteria in the future, this is the only product you should be purchasing." Your website also states, "The Antidote can be taken safely with any current medication you may be using."

Your website also contains personal testimonials that constitute therapeutic claims. These testimonials include, but are not limited to, the following:

1. [redacted] states that he "had a lung infection," and "after about 80 hours, my lungs seemed to have cleared out and working freely. Also, this product (at least in my case) is working as an excellent anti-smoking agent."
2. [redacted] states that she had been diagnosed with Parkinson's Disease in 1990, and "The Antidote has done its work on parasites, polarity, biological warfare, viruses, bacteria, candida and even Parkinson's disease."

* Actual names have been removed.

3. [redacted] states, " I took my Antidote and have rid my self of the things listed below:
    - Candida
    - Fever blisters
    - Constant sore throat
    - Nasal drainage on the back of throat"

"The Antidote" is offered for sale to U.S. citizens and the "Order" page of the website provides for payment and shipment to U.S. addresses. Indeed, the website testimonials are from persons residing in the United States. This product appears to be available to anyone who orders the product from your website.

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 U.S.C. 355(i); 21 CFR Part 312). Your product is not the subject of an approved biologics license application (BLA) or an investigational new drug application (IND). Therefore, your shipments of product for which a valid license or IND is not in effect represent violations of the Act and the PHS Act and may result in the Agency seeking such relief as provided by law. (21 U.S.C. 331).

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