



APR - 9 2002

8 3 7 4 '02 APR 12 P1:35

Mr. William Moeller  
President  
American Biotech Labs  
70 West Canyon Crest Road  
Alpine, Utah 84020

Dear Mr. Moeller:

This is in response to your letter of March 19, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that American Biotech Labs is making the following claim for the product **ASAP Sporicidal Strength, a silver supplement**:

“Scientifically proven to kill bacteria and spores.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product, including the use of the term “sporicidal” in its name, suggests that it is intended to treat, prevent, or mitigate diseases caused by pathogenic bacteria. Moreover, you included information in your submission that indicates you have tested this product’s sporicidal properties against anthrax spores, suggesting that you intend to promote the product as being effective in killing *Bacillus anthracis* and/or inactivating its spores. The claims in your submission, and any implied or express claims about the product’s effectiveness against *B. anthracis* or its spores that you may intend to make, do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if you require further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling,  
and Dietary Supplements

Center for Food Safety

and Applied Nutrition

**Copies:**

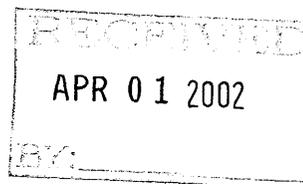
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Denver District Compliance, HFR-SW240 -

March 19, 2002

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C St. SW.  
Washington, DC 20204



Office of Special Nutritionals:

Based upon Title 21 Section 101.93 of the Code of Federal Regulations (revised version of April 1, 2000) I hereby certify that this letter shall serve as notice to the Office of Special Nutritionals, Center for Food Safety and Applied Nutrition for the following:

Manufacturer Name: American Biotech Labs  
70 West Canyon Crest Road  
Alpine, UT 84020  
(801) 756-1414 P.  
(801) 756-5454 F.

Name of Dietary Supplement: ASAP Sporicidal Strength, a silver supplement

Ingredients: Purified silver, purified water

403 (r) (6) Statement: "Scientifically proven to kill bacteria and spores."

Disclaimer on Label: "The statement concerning the sporicidal and bactericidal properties of this product has not been evaluated by the U.S. Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Attached hereto are copies of three different independent test results validating the veracity of the statement that this product has been proven to kill bacteria and spores. In addition, attached is a copy of the actual label used to market this product.

A handwritten signature in black ink that reads "William Moeller".

William Moeller  
President  
AMERICAN BIOTECH LABS

Two Copies Included Herein