

Cover Letter

— PHOENIX —

REGULATORY ASSOCIATES, LTD.

Washington DC Headquarters

21525 Ridgetop Circle

Suite 240

Sterling, Virginia 20166

European Office: Dorset, England

March 25, 2005



Linda Pellicore, Ph. D., Supervisory Toxicologist
Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

VIA: Federal Express

Re: Clarification Amendment for New Dietary Ingredient Notification for enzyme-treated
Agaricus blazei Murill mycelia (ABPC®)

Dear Ms. Pellicore:

Japan Applied Microbiology Research Institute, Ltd., (JAMRI) submits the original and two copies of the March 18, 2005 response that we provided you by facsimile as a result of our March 15, 2005 teleconference with you and Dr. Dan Levy.

The March 18, 2005 cover letter from Phoenix Regulatory Associates, Ltd. is included in Appendix 1. The March 18, 2005 clarification statement from Mr. T. Suyama, JAMRI is included in Appendix 2.

The original certification statements that the English translations are word for word from the original Japanese texts are in Appendices 3 (Stephanie Benefield), 4 (Takeru Suyama), and 5 (Kenji Yoshida). You will note that Mr. Suyama amended his earlier statement that I faxed on March 18. He corrected the statement to include translation of the three short-term toxicological studies (acute, Ames, and *in-vitro* chromosomal aberration).

The MSDS for the brewer's yeast is located in Appendix 6.

The available MSDS for ingredients used in the culture media are located in Appendices 7 (yeast extract), 8 (malt extract), 9 (hemicellulase) and 11 (sugar).

The MSDS for ethanol is located in Appendix 10. Ethanol is diluted to a 70% mixture and used for sterilizing the equipment and containers used for freeze-drying the mycelia-yeast mixture.

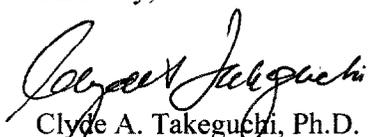
The MSDS for ingredients used in the tablet are located in Appendices 12 (lactose) and 13 (sugar ester).

—————PHOENIX—————
REGULATORY ASSOCIATES, LTD.

Linda Pellicore, Ph. D., Supervisory Toxicologist
Re: Clarification Amendment for New Dietary Ingredient Notification for ABPC®
March 25, 2005
Page Two

If there are any questions, please contact me at (703) 406-0906 or at
phoenix@phoenixrising.com.

Sincerely,



Clyde A. Takeguchi, Ph.D.
Phoenix Regulatory Associates, Ltd.
U.S. Agent for
Japan Applied Microbiology Research Institute Ltd.

Enclosure: (original and two copies of Amendment for 75-day Notification)

cc: Japan Applied Microbiology Research Institute Ltd.