





JAPAN APPLIED MICROBIOLOGY RESEARCH INSTITUTE LTD.

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March 8, 2005

Barbara O. Schneeman, Ph.D.  
Office of Nutritional Products, Labeling  
and Dietary Supplements (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

Re: Courier

RE: Notification under Section 8 of DSHEA and 21 CFR 190.6

MAR 10  
AB/ROA

Dear Dr. Schneeman:

This notification is filed in accordance with 21 U.S.C. 350b(a)(2) [§413(a)(2) of the Federal Food, Drug, and Cosmetic Act] and 21 CFR 190.6, Requirement for premarket notification by Japan Applied Microbiology Research Institute, Ltd., (JAMRI) 326 Otoguro Tamaho-cho, Nakakoma-gun, Yamanshi, 409-3812, Japan.

The new dietary ingredient, ABPC<sup>®</sup>, is an enzyme-treated *Agaricus blazei* Murill mycelia mixed with brewer's yeast. The manufacturing process is in accordance with Current Good Manufacturing Practice and ISO 9001 for design, developing, and manufacturing of product.

JAMRI has concluded that ABPC<sup>®</sup> is safe for use as a new dietary ingredient, and has provided the history of use of ABPC<sup>®</sup> and safety information from *in-vitro* studies and animal studies that support the safety of ABPC<sup>®</sup>.

Portions of this notification are considered commercial confidential and fall within the exemptions established in §20.61 (21 CFR 20.61) of the Code of Federal Regulations.

If there are any questions, please contact Clyde A. Takeguchi, Ph.D., Phoenix Regulatory Associates, Ltd. at (703) 406-0906 or at phoenix@phoenixrising.com.

Sincerely,

Takeru Suyama, Director  
Japan Applied Microbiology Research Institute Ltd.

Attachment: 75-Day notification (original and two copies)