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# PHOENIX REGULATORY ASSOCIATES, Ltd.

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**TO:** Office of Nutritional Products, Labeling And Dietary Supplements  
**ATTENTION:** Linda Pellicore, Ph. D. (HFS-810)  
**FROM:** Clyde Takeguchi, Ph. D.  
**FAX NUMBER:** (301) 436-2636  
**DATE:** March 18, 2005  
**cc:**  
**NUMBER OF PAGES:** 27  
**SUBJECT:** Re: Clarification Amendment for New Dietary Ingredient Notification for enzyme-treated *Agaricus blazei* Murill mycelia (ABPC®)

Dear Linda:

We have attached our response to your questions regarding the New Dietary Ingredient Notification for ABPC®.

I hope that the attached information will resolve your questions and clarify the information in the Notification.

If you have any questions, please call me at (703) 406-0906.

Sincerely,

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— PHOENIX —

REGULATORY ASSOCIATES, LTD.

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March 18, 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

Re: Facsimile  
Original by Mail

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

Dear Ms. Pellicore:

Japan Applied Microbiology Research Institute, Ltd., (JAMRI) submits this letter to clarify its New Dietary Ingredient Notification that it submitted on March 8, 2005. In a March 15, 2005 teleconference with you and Dr. Dan Levy, you requested that: (1) the identity of the new dietary ingredient and the dietary supplement, including any ingredients used be identified and clarified; (2) clarify what substance was used in the toxicological tests; and (3) provide a certification from the translator that each translated document is an accurate word for word translation.

1. Identity

The new dietary ingredient is the enzyme-treated *Agaricus blazei* Murill mycelia mixed with brewer's yeast. This ingredient is called ABPC<sup>®</sup>-FD, which is the freeze-dried mixture of the mycelia MSDS for the production media ingredients and the enzyme, are attached. (The MSDS for peptone, a GRAS ingredient, is available only in Japanese and is not attached.)

The granules which will be sold as a dietary supplement product and labeled as ABPC<sup>®</sup> are identical to ABPC<sup>®</sup>-FD. (See Table 1, p. 2 of Notification.)

The ABPC<sup>®</sup> tablets include safe and suitable excipients used in the manufacture of dietary supplements and drug products. Standard composition of ABPC<sup>®</sup> tablets

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

Linda Pellicore, Ph. D., Supervisory Toxicologist  
Re: Clarification Amendment for New Dietary Ingredient Notification for ABPC®  
March 18, 2005  
Page Two

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2. Test substance

ABPC®-FD from one lot was used for all safety tests.

Lot No.	SUG-003
Production date	January 29, 2004

3. Certification

We have attached signed statements from the translators that the translation was a complete, word for word translation of the relevant documents. You will note that the letter from Mr. Takeru Suyama mentions the Ames reverse mutation test twice. This is an oversight and we have asked him to include the *in vitro* chromosomal aberration test to the list of documents that he translated.

90 Day study protocol and report	Ms. Stephanie Benefield
Single dose rat and <i>in vitro</i> studies	Mr. Takeru Suyama
Iwade article	Mr. Kenji Yoshida

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 plus attachments)

- 1) JAMRI response, March 18, 2005 from Mr. Suyama to Dr. Takeguchi
- 2) Certifications:

Benefield  
Suyama  
Yoshida

- 3) MSDS:

For media: Dried brewery yeast Y3, Meast powder K, Malt extract powder,  
hemicellulase, alcohol, White soft sugar  
For tablets: Lactose, sugar ester