



# Food Distribution Laboratory Corporation

1-15-1 Higashi Ikebukuro, Hishiyama Bldg. 6<sup>th</sup> Fl.

Toshima-Ku, Tokyo 170-0013, Japan

TEL: 81-3-5954-9703 FAX: 81-3-5954-9701

1125 11/19/03

November 12, 2003



Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy.  
College Park, MD 20740

To Whom It May Concern:

Pursuant to section 403(r)(6) of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Food Distribution Laboratory Corporation, located at 1-15-1 Higashi Ikebukuro, Hishiyama Bldg 6<sup>th</sup> Fl., Toshima-Ku, Tokyo 170-0013, Japan, hereby notifies the Food and Drug Administration that it is marketing a dietary supplement that bears a nutritional support statement on its label.

Product Name: Shin Sei Ju

Company Name: Food Distribution Laboratory Corporation

Address: 1-15-1 Higashi Ikebukuro, Hishiyama Bldg. 6<sup>th</sup> Fl  
Toshima-Ku, Tokyo 170-0013  
Japan

Statements on the Label:

Ingredients:

Agaricus Blazei Murril Extract, Beer Yeast

Nutrition Facts: 1 packet/ 1.5 g 5.7 kcal

Protein: 495.0 mg ( 19.9 mg of Beta-D-Glucan contained)

Fat: 34.5 mg Carbohydrates: 853.5 mg Water: 40.5 mg Ash: 76.5 mg

Structure Function Claim:

Beta-D-Glucan contained in protein is known to boost the immune system.

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### Suggested Use:

Take one to two packets per day, as a dietary supplement

Do not take after the expiration date.

### Suggested Storage:

Store in a cool. Avoid exposure to direct sunlight and moisture.

### Other Information:

No preservatives or artificial coloring are used.

These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

As required, the original and two copies of this notification are enclosed.

I hereby certify that the information contained in this notice is complete and accurate, and that Food Distribution Laboratory Corporation has substantiated that the statements are truthful and not misleading.

If you have any questions regarding this information, please contact the undersigned at 81-3-5954-9703 or e-mail at : [y\\_tanaka@t-surpass.co.jp](mailto:y_tanaka@t-surpass.co.jp).

Sincerely,

A handwritten signature in cursive script that reads 'Y. Tanaka'.

Yoshio Tanaka

President

Food Distribution Laboratory Corporation