



SUNDORY CO., LTD.

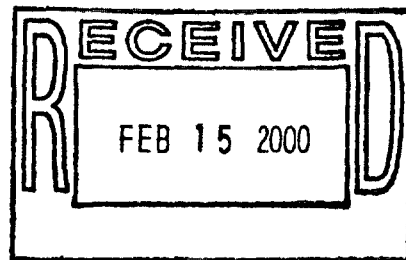
HEAD OFFICE:
6-964, NAKAMOZU-CHO
SAKAI-CITY, OSAKA, JAPAN
TEL: (0722)57-8568
FAX: (0722)57-8655

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PREMARKET NOTIFICATION

November 10, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W., Washington, D.C. 20204



The Content of Notification:

As required by the U.S. Code of Federal Register (21 CFR 101.93) SUNDORY COMPANY, LTD. HEAD OFFICE located at 6-964 Nakamozu-Cho, Sakai City, Osaka, Japan hereby would like to submit a Premarket Notification to the Office of Special Nutritionals (HFS-450), Center for Food Safety and Applied Nutrition, Food and Drug Administration, Washington, D.C. 20204.

(i) The product "Kyowa Agaricus Sen-Sei-Ro (*Agaricus Blazei Murill*) Extract Gold" is a water extract from cultured natural mushroom (*Agaricus Blazei Murill*) and is recommended as a natural dietary supplement for maintaining general well being*. "Sen-Sei-Ro, Extract" and "Sen-Sei-Ro, Granules Gold" are manufactured in compliance as required by Japanese Good Manufacturing Practice (JGMP) by KYOWA ENGINEERING Co., LTD. a member of KYOWA HAKKO Group, Tokyo, Japan. The product is distributed exclusively by SUNDORY COMPANY, LTD, 6-964, Nakamozu-Cho, Sakai City, Osaka, Japan (Tel: 81-722-57-8568; Fax: 81-722-57-8655).

(ii) The package labeling is as follows:

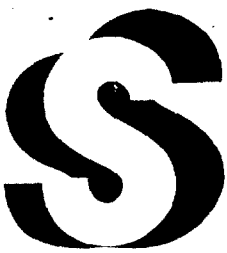
Suggested use:

As a dietary supplement take one to three packets per day. Liquid type (50 ml per pack). Shake well before opening the packs and pour into a glass and drink, or mix with any type of juice or soft drink, For the powder type (1.7g per pack), pour the content into a glass of water or other type drink, and mix well and drink.

"Sen-Sei-Ro" has been frequently recommended for maintenance of general health through modulation of homeostasis.

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LET 4945



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Ingredients: Edible mushroom (*Agaricus blazei* Murill) standardized extract or powder.

Nutritional Facts:

Standard nutritional contents per each dried edible mushroom (*Agaricus blazei* murill) (100 g):

Vitamins: vitamin B₁(ThiamineHCL)0.84mg, vitamin B₂(Riboflavin)3.38mg, vitamin D₂90IU, pantothenic acid 20.6mg, Biotin 65.2ug, Inositol 270mg, Niacin 34.1mg, Choline 0.37g,

Minerals: Phosphate 830mg, iron 6.94mg, calcium 10.5mg, sodium 6.6mg, potassium 2.52g, magnesium 76.3mg, copper 5.64mg, zinc 7.42mg, manganese 638ug, cobalt 0.2ppm, chlorine 537mg, silicon 24ppm, aluminium 19ppm, sulfur 0.3mg,

Amino acids: arginine 1.37g, lysine 1.39g, histidine 0.56g, phenylalanine 0.95g, tyrosine 0.68g, leucine 1.62g, isoleucine 0.96g, methionine 0.34g, valine 1.16g, alanine 1.53g, glycine 1.14g, proline 1.06g, glutamic acid 4.86g, serine 1.07g, threonine 1.10g, aspartic acid 2.09g, tryptophan 0.34g, cysteine 0.32g.

Water:(3.4 g), Protein(37.4g), Fats(3.4g), Carbohydrates(55.8g)
sodium(6.0mg). Water(3.4g),.

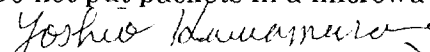
Other information:

Neither preservatives nor artificial color is used. Only natural ingredients are used. If you experience any problems with this product, please return it for a replacement.

*These statements are not approved by the US, FDA. This product is intended to be used as only a dietary supplement. It is not intended to diagnose, treat, or cure any disease.

Caution: Do not put packets in a microwave oven, or contact with open flame.

Signed



Yoshio Kawamura

President, Sundory Co., LTD.

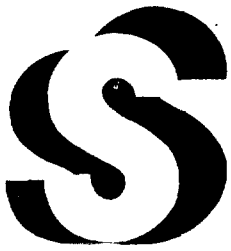
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