



American Institute for **Biosocial** and **Medical Research**, Inc.
Natural and Medicinal Products Research

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December 18, 2003

Dr. Susan Walker, PhD
Division of Supplement Programs and Compliance,
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820),
Center for Food Safety and Applied Nutrition (CFSAN),
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Dr. Walker:

Please add the enclosed letter to the 75-day pre-market notification filed by AIBMR, Inc. on December 17, 2003. on behalf of:

Smith Naturals Co. Ltd.
90 Fifti-Fifth Plaza, Soi Thonglor 2,
Sukhumvit 55 Road, North Klongtan,
Wattana, Bangkok 10110, Thailand

The name of the dietary supplement that is the subject of the premarket Notification is:

An extract of *Pueraria candollei* var. *mirifica* Airy Shaw & Suvatabandhu root powder
(hereinafter called Pueraria mirifica extract).

Sincerely,

Richard Conant

86794

AB/FDA

December 17, 2003

Dr. Susan Walker, PhD
Division of Supplement Programs and Compliance,
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820),
Center for Food Safety and Applied Nutrition (CFSAN),
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Dr. Walker:

We have been authorized, as evidenced by the attached letter by Smith Naturals Co. Ltd., in Bangkok, Thailand, to submit a premarket New Dietary Ingredient Notification on its behalf, as required under 21CFR190.6.

This New Dietary Ingredient Notification presents comprehensive scientific information that is the basis on which Smith Naturals has concluded that *Pueraria mirifica* extract will reasonably be expected to be safe, as required by 21CFR 190.6 (b) (4). The format of this Notification meets the requirements listed in 21CFR 190.6 (b) (1 through 5).

Our street mailing address for communications is:

Attention: Richard Conant
V.P. Technical and Regulatory Affairs
Life Sciences Division,
AIBMR, Inc.,
4117 S. Meridian,
Puyallup, WA 98373
Phone: 253-286-2888
FAX: 253-286-2886

The name and address of the manufacturer is:

Smith Naturals Co. Ltd.
90 Fifty-Fifth Plaza, Soi Thonglor 2,
Sukhumvit 55 Road, North Klongtan,
Wattana, Bangkok 10110, Thailand

The name of the dietary supplement that is the subject of the premarket Notification is:

An extract of *Pueraria candollei* var. *mirifica* Airy Shaw & Suvatabandhu root powder (hereinafter called *Pueraria mirifica* extract).

The conditions of use for *Pueraria mirifica* extract:

- 1) The suggested daily intake on the product label is 80 milligrams a day, in two servings of 40 milligrams.
- 2) The serving size is one capsule or tablet containing 40 mg of Pueraria mirifica extract.
- 3) Suggested use: Take one capsule/tablet two times a day with food.
- 4) The product will be marketed to post-menopausal women as a dietary supplement for maintenance of normal body function.
- 5) The history of use and evidence of safety, that is the basis on which Pueraria mirifica extract will reasonably be expected to be safe for use under the above conditions, are detailed in the brief and appended document submitted with this Notification.

Sincerely,

A handwritten signature in black ink that reads "Richard Conant". The signature is written in a cursive, flowing style.

Richard Conant
Vice President,
Technical and Regulatory Affairs

Enclosures: One original and two copies of the NDI submission



19 September 2003

Dr. Alexander Schauss
American Institute for Biosocial & Medical Research
4117 South Meridian
Puyallup, WA 98373
USA

Dear Alex,

This letter authorizes you and / or designated staff members of AIBMR; to handle all FDA related matters, regarding the NDI submission.

Sincerely,

A handwritten signature in black ink, appearing to read "I. Sanford Schwartz". The signature is written in a cursive, somewhat stylized script.

Dr. I. Sanford Schwartz
Chief Executive Officer

SMITH NATURALS Co L¹
90 Fifty-fifth Plaza
Sukumvit 55 Road
Bangkok 10110
Thailand
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