

MACA US Sales

12130 NW46 Street, Coral Springs, FL 33076
954-755-9461 (Phone), 954-599-5348 (Cell), 954-755-9461 (Fax), shaoxudong@yahoo.com

Thursday, April 17, 2003

2482 '03 MAY -5 P1:59

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

APR 24 2003

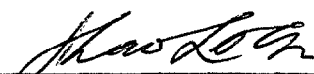
RE: Dietary Supplement Statement of Support Notification

To Whom It May Concern:

MACA Caval Power US Sales, 12130 NW46th Street, Coral Springs, FL 33076, the distributor of the following dietary supplement products, intends to make the following statement of support: “MACA (Lepidium meyenii Walp.) is an Andean root crop used as a food staple and herbal medicine in South America. It was domesticated 2000 years ago by the Inca Indians due to its high nutritional value and it was commended by international dietitians as a source of nourishment. In the middle of 1990s, as a natural dietary supplement, MACA was produced primitively by American scientists with advanced biotechnology.” “Function: Anti-fatigue.”

This claim is being made for MACA (Lepidium meyenii Walp.), which is contained in MACA™ CAVAL POWER CAPSULES 300 mg, manufactured by MACA Bioengineering (HUBEI), Ltd. and MACA Bioengineering, Inc. (USA), who is supervising the production process. This submission is made in compliance with the requirement of 21 CFR 101.93.

The undersigned is an authorized sales representative of MACA Bioengineering (HUBEI), Ltd and certifies that the information contained in this notice is complete and accurate, and that MACA Bioengineering (HUBEI), Ltd has substantiation that the above statement is truthful and not misleading.



Signature
SHAO, XUDONG

Full Name
MACA™ US Sales/Distributor
Title

Enclosures

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LET

11913

84175

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Center for Food Safety and Applied Nutrition
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200 C Street, S.W.
Washington, DC 20204

RE: Dietary Supplement Statement of Support Notification

To Whom It May Concern:

This letter is submitted pursuant to Section 406 (r)(6) of the Federal Food, Drug, and Cosmetic Act for the purpose of notifying the agency of statements being made in connection with the marketing of dietary supplements being distributed by this representative.

The product name and the dietary ingredients for which the statement is being made are as follows:

MACA™ CAVAL POWER CAPSULES 300 mg
MACA (*Lepidium meyenii* Walp.) – 100% purely natural herb
Other Ingredients: 7.6 g amino acid, 0.077 g taurine, 0.0027g zinc per 100g material

Manufacturer: MACA Bioengineering (HUBEI), Ltd. (P. R. China) and MACA Bioengineering, Inc. (USA), who is supervising the production process

Addresses: Bamboo Garden Building, No. 146, East Lake Rd., Wuhan, China
6510-F Clavell Lane, Charlotte, NC 28210, USA

The text of the statements that are being made in regards to the above stated product are listed below:

- MACA (*Lepidium meyenii* Walp.) is an Andean root crop used as a food staple and herbal medicine in South America. It was domesticated 2000 years ago by the Inca Indians due to its high nutritional value and it was commended by international dietitians as a source of nourishment. In the middle of 1990s, as a natural dietary supplement, MACA was produced primitively by American scientists with advanced biotechnology
- Function: Anti-fatigue; Applicable group: Fatigable and weak people
- 100% purely natural premium quality herb

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- This product is not intended to prevent, treat, cure or mitigate any disease

The above statements may be used in both English and Chinese, as shown in the attachment, and two language versions should carry same exact meanings.

The undersigned is an authorized sales representative of MACA Bioengineering (HUBEI), Ltd and certifies that the information in this notice is complete and accurate, and MACA Bioengineering (HUBEI), Ltd has substantiation that the above statement is truthful and not misleading.

Sincerely,



Xudong Shao
MACA™ US Sales/Distributor

Enclosures ,

300mg

Function: antifatigue

*Maca Bioengineering Inc(USA)
(supervising the production process)*

USA

100%purely natural
premium quality herb

24 capsules
per bottle
Antifatigue

MACATM

**MACA CAVAL POWER
CAPSULE**

300mg

保健作用：抗疲劳

玛雅生物工程(湖北)有限公司(出品)
美国玛雅生物工程有限公司(监制)

USA

100%纯天然

24 capsules

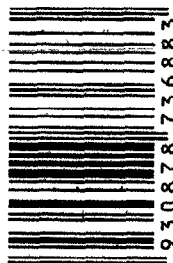
per bottle
Antifatigue

MACATM

玛咖骑力胶囊

MACA™

玛咖精力胶囊



6 930878 736883

MACA (*Lepidium meyenii* Walp.) is an Andean root crop used as a food staple and herbal medicine in South America. It was domesticated 2000 years ago by the Inca Indians due to its high nutritional value, and it was commended by international dietitians as a source of nourishment. In the middle of 1990s, as a natural dietary supplement, MACA was produced primitively by American scientists with advanced biotechnology.

[Main material] 100% purely natural herb—MACA (*Lepidium meyenii* Walp.)

[Function Ingredients & Content] 7.6g amino acid, 0.077g taurine, 0.0027g zinc per 100g material

[Function] antifatigue

[Net content] 300mg per capsule

[Specification] 60 capsules per bottle

[Applicable people] fatigable and weak people

[Inapplicable people] children

[Dosage] 3 capsules once, twice per day

[Store] please keep in cool and dry places

[Notice] this product is not intended to prevent, treat, cure or mitigate any disease

[Term of validity] 24 months (date of production: see the bottle bottom)

[Executing standard] Q/MSH001-2001

【主要原料】

玛咖(MACA, *Lepidium meyenii* Walp.)块根粉末

【功效成份】

每100g胶囊中含: 氨基酸7.0g、牛磺酸0.077g、锌0.0027g

【保健作用】

抗疲劳

【适宜人群】

易疲劳者

【不适宜人群】

少年儿童

【食用方法】

每日口服2次, 每次3粒

【产品规格】

0.3g/粒, 60粒/瓶 24粒/盒

【保质期】

24个月(生产日期见瓶底)

20020801

【贮藏方法】

置于阴凉干燥处

【执行标准】

Q/MSH001-2001

公司名称: MACA BIOENGINEERING(HUBEI)LTD.

玛雅生物工程(湖北)有限公司

地址: Bamboo Garden Building No.146 East Lake Road

Wuhan China

中国武汉市东湖路146号竹园楼

邮编: 430077

热线电话: 027-86773702 86773703 86773705

传真: 027-86773704

公司名称: Maca Bioengineering Inc, USA

美国地址: 6510-F Clavell Lane Charlotte, Nc 28210

电话: 001-704-556-1056

传真: 001-704-556-7457

MACA™

玛咖精力胶囊

<http://www.maca.com.cn>



OPEN HERE

注意: 本品不能代替药品

MACA

TM



ENGINEERING

MACA

Function: antifatigue

300 mg

USA

100% purely natural
premium quality herb

24 capsules
per bottle
Antifatigue

MACA CAVAL POWER
CAPSULE

Maca
(superv)

