DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

2560 '03 MAR 20 P2:05

APR 2 2003

Mr. Paul Castillo
Manager
Gano Excel (U.S.A.) Inc.
4981 North Irwindale Avenue
Suite 800
Irwindale, California 91706

Dear Mr. Castillo:

This is in response to your original notification to the Food and Drug Administration (FDA) dated October 25, 2002, making a submission for a new dietary ingredient pursuant to 21 U.S.C. 350b(a)(2) (section 413 of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 190.6. On December 6, 2002, we notified you that the submission was inadequate in accordance with 21 CFR 190.6. On January 13, 2003, you submitted additional information to FDA. Your notification notified FDA of your intent to market products containing an extract from the mushroom *Ganoderma lucidum*, a substance that you assert is a new dietary ingredient. Your submission indicates that you intend to market:

- Ganoderma™ Capsules that you assert contain "100% mature mushroom (ninety day old)" and are "freeze dried in powder form and packaged in capsule form."
- Excellium™ Capsules that you assert contain "100% young mushroom (30 days old)" and are "freeze dried in powder form and packaged in capsule form."
- Garcinia™ Capsules that you assert contain "5% Ganoderma lucidum extract," and the "natural tropical fruits, *Garcinia atroviridis, Garcinia cambogia and Tamarindus indica*."
- Sakanno™ Capsules that you assert contain 5% *Ganoderma lucidum* and *Eurycoma longifolia* Jack.

Under 21 U.S.C. 350b(a)(2), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

955-0316

RPT165

FDA has carefully considered the information in your submission and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing *Ganoderma lucidum* will reasonably be expected to be safe.

The amended Notification contains statements that Gano Excel Industries, SDN, BHD, Malaysia, has been selling Sakanno capsule 300 mg and Gano Garcina capsule 410 mg since 1999 and Ganoderma capsule 275 mg and Excellium capsule 425 mg since 1996. The amended Notification also contains a statement from PanGlobal Insurance Berhad that Gano Excel Enterprise Sdn Bhd/Gano Excel Industries Sdn Bhd have insured their foodstuff/food supplements since 1997 and no claims have been made by them.

No data or other information are provided with the amendment that would support a safety evaluation of the product.

The information included in the amended notification provides evidence of prior use of the four products listed above. It is not clear whether the four products mentioned above are the same as those mentioned in the original notification and intended for marketing. The information provides no information that these substances are qualitatively and quantitatively similar to the proposed new dietary ingredients. Additionally, in the earlier notification inclusion of extracts in two of the products was mentioned. There is no mention of extracts in the amendment and there is no information that specifically addresses issues of safety. The information submitted does not provide evidence supporting the safe use of the products in part because the information provided in the amendment does not adequately relate the products mentioned to those included in the earlier notification.

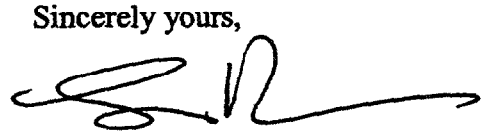
Therefore, your submission does not provide an adequate basis to conclude that the use of dietary supplements that contain the ingredients identified in your notification will reasonably be expected to be safe. Therefore, your products may be adulterated under 21 U.S.C. 342(f)(1)(B) as dietary supplements that contain a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

We have enclosed a copy of section 21 CFR 190.6 for your future reference. You also may wish to review FDA's Web site at http://www.cfsan.fda.gov/~dms/ds-ingrd.html for additional details on new dietary ingredient notification requirements.

Your submission will be kept confidential for 90 days from the date of receipt, and after April 17, 2003, your submission will be placed on public display at Dockets Management Branch (Docket No. 95S-0316). Commercial and confidential information in the notification will not be made available to the public.

Please contact us if you have questions concerning this matter.

Sincerely yours,



Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

GANO EXCEL (U.S.A.) INC.

4981 North Irwindale Avenue, #800
Irwindale. CA. 91706
Tel. No. 604-614-6260 Fax No. 604-856-1292

January 13, 2003

Ms. Felicia B. Satchell
Director,
Food and Drug Administration
Division of Standards and
Labeling Regulations
Office of Nutritional Products.
Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740

Dear Ms. Satchell,

As per your letter of December 6, 2002. We hereby submit an amendment to our submission of October 25, 2002. As requested we submit herewith proof that our products has been in the market since 1997 in Malaysia. Also enclosed are the following:
Copy of letter from PanGlobal Insurance
Copy of letter from Gano Excel Industries Sdn. Bhd.
Copy of letter from Gano Excel
Certificate of Product Registration with the Bureau of Food & Drug (Philippines)
Certificate of Product Registration with the Bureau of Food & Drug (Malaysia)

We also submit the exact ingredient and formulation of each product as requested. We also noticed that other companies have submitted Ganoderma Lucidum as new dietary ingredient as far back as 1998 submitted by P & Y Dietary Supplements, Inc. as shown on your website listings of submissions.

We sincerely hope that the above submission will meet your requirements.

Yours truly,

Gano Excel (U.S.A.) Inc.

Paul Castillo
Manager

PC:nc

RECEIVED 1/17/03

GANO EXCEL INDUSTRIES SDN. BHD. (540951-H)
94, 95, 96, Kawasan Perusahaan Tandop Baru, Jalan Tunku Abdul Rahman,
06050 Alor Setar, Kedah, Malaysia.
Tel : 04-7713885 Fax : 04-7712526

To Whom It May Concern

Product : GANODERMA

INGREDIENTS	INGREDIENTS PER 100G	PERCENTAGE
Ganoderma	100g	100.00%

鴻翔工業有限公司
GANO EXCEL INDUSTRIES SDN. BHD. (540951-H)
94, 95, 96, Kaw. Perusahaan Tandop Baru,
Jalan Tunku Abdul Rahman,
06050 Alor Setar, Kedah, Malaysia.
Tel/Fax: 604-771 3086

GANO EXCEL (U.S.A.) INC.

Suite 800 Irwindale Business Center
4981 N. Irwindale Avenue,
Irwindale, CA. 91706

Tel. No. 604.614.6260 – Fax No. 604.856.1292 Email: pcastillo@ganoexcel.ca www.ganoexcel.com

Oct 25/02

Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS—820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD, 20740-3535

Re: **PREMARKET NOTIFICATION**

Gentlemen:

We hereby submit the following new dietary ingredient in our products:

GANODERMA LUCIDUM extract from the red Chinese mushroom.

The **GANODERMA™ CAPSULES** contains 100% mature mushroom (ninety day old) freeze dried in powder form and packaged in capsules form. The **EXCELLIUM™ CAPSULES** contains 100% young mushroom (30 days old) freeze dried in powder form and packaged in capsules form. These ingredients react naturally with the human body without any side effects. These products are used to help people feel more energetic. Food supplement for vitamins and minerals.

Our product **GARCINIA™ CAPSULES** also contains 5% Ganoderma Lucidum extracts and also includes the following ingredients: Natural tropical fruits Garcinia Atroviridis, Garcinia Cambogia and Tamarindus Indica. These are extract from fruits of the same name. These ingredients react naturally with the human body without any side effects. This product is used to help people control their appetite.

Our product **SAKANNO™ CAPSULES** also contains Tongkat Ali scientifically known as Eurycoma Longifolia Jack extract and 5% Ganoderma Lucidum. This product helps people gain that extra energy. Food supplement for vitamins and minerals.

B.J.S

Above products are manufactured by:
GANO EXCEL ENTERPRISE SDN. BHD.
No. 3 Susuran Shahab, Shahab Perdana, Jalan Sultanah Sambungan,
05150 Alor Setar, Kedah. Malaysia
Tel. No. 604-734-6828 Fax No. 604-732-3828

Above products have been produced since 1995 under Good Manufacturing Practice (GMP), approved by the Control of Drug Authority, Ministry of Health Malaysia. Australian Quarantine and Inspection Service, Department of Agriculture, Fisheries and Forestry. Approved by the Republic of Singapore, Ministry of Health as Chinese Proprietary Medicines.

These products have been in use by thousands of people in Malaysia, Thailand, India, Philippines, Myanmar, Singapore, Indonesia, Australia, Hong Kong and Canada. All products are considered safe.

We hereby submit all of the above products for pre-market approval. Please contact the undersigned for any questions at (604) 614-6260.

Thank you for your prompt attention.

Yours truly,

GANO EXCEL (U.S.A.) INC.

Paul Castillo
Manager

ORIGINAL

LICENCE NO.
CPMI0026

CONDITIONS

1. Any subsequent change in the name, store address and storage conditions of the licence holder will render the licence invalid unless prior approval for the change has been obtained from the licensing authority.

2. Any subsequent changes in any other particulars set out in the application form relating to the licence holder or to the person who made the application for the licence on behalf of the licence holder must be reported to the licensing authority immediately upon the change.

3. A record of receipts, and wholesale sales of each Chinese Proprietary Medicine dealt with under the licence shall be kept in the format as stated in Appendix I or otherwise recorded so as to provide the same particulars required in the Appendix.

4. Any change in the following particulars of the Chinese Proprietary Medicine dealt with under the licence must be approved by the licensing authority prior to such change being made : (a) product name and trade / brand name (b) product formula (c) dosage form (d) name and address of manufacturer / assembler (e) content of label(s) / package insert.

Pihak Berkuasa Kawalan Dadah
Drug Control Authority
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Our Ref : (19) dlm. BPFK/30/12/4003
Date : 10th November 2000.

The National Control Bureau (NPCB), Ministry of Health Malaysia hereby certifies that the following manufacturer :

Name : Gano Excel Enterprise Sdn. Bhd.

Address : Plot 92, Kawasan Perusahaan Mergung
Barrage Fasa 2B, Mukim Mergung
05350 Alor Setar, Kedah
Malaysia

has been subjected to a Good Manufacturing Practice (GMP) audit for the manufacture of Traditional Medicine by officers from National Pharmaceutical Control Bureau. From the audit report, it was found that the manufacturer has an overall acceptable level of compliance to the Malaysian GMP, as laid down in accordance with the recommendation of the World Health Organisation.

(EISHAH ABDUL RAHMAN)
Head of GMP and Licensing Division
For Director
National Pharmaceutical Control Bureau
Ministry of Health Malaysia.

This document is valid till 9th November 2002.

SH/Mgy

FORM 1

CONTROL OF DRUG AND COSMETIC REGULATIONS 1984

[Regulation 8(8)]

CONTROL OF DRUG AUTHORITY
MINISTRY OF HEALTH MALAYSIA

REGISTRATION

No. 029476

REGISTRATION NO : MAL19992490T

Name & Address Of Holder :

GANO EXCEL ENTERPRISE SDN. BHD.
K168, TMN WIRA MERGONG, 1ST FLR, JLN SULTANAH SAMBUNGAN,
06360 ALOR SETAR, KEDAH.

DETAILS OF PRODUCT:

Name	:	**SAKANNO (GANO TONGKAT ALI) CAPSULE**
Name Of Producer	:	**K168, TMN WIRA MERGONG**
Address Of Producer	:	**1ST FLR, JL SULTANAH SAMBUNGAN 06360 ALOR SETAR, KEDAH.**
License No.	:	–

This is the True and Correct Translation of the Document produced in Serial No. 2 601

Sworn Interpreter
High Court,
Alor Setar.
KEDAH
MALAYSIA

The above product is being registered according to the following requirements:

ALL REQUIREMENTS WHICH HAS BEEN APPROVED BY THE CONTROL OF DRUG AUTHORITY.

Period of this registration is from **30th September, 1999 to 30th September, 2004.**

Signed.
TAN SRI (DR.) ABU BAKAR BIN DATO' SULEIMAN
Chairman
Control Of Drug Authority

Previous Registration No. :
Date Issued :

FORM 1

CONTROL OF DRUG AND COSMETIC REGULATIONS 1984

[Regulation 8(8)]

CONTROL OF DRUG AUTHORITY
MINISTRY OF HEALTH MALAYSIA

REGISTRATION

No. 011097

REGISTRATION NO : MAL19961984T

Name & Address Of Holder :

GANO EXCEL ENTERPRISE SDN. BHD.
K168, 1ST FLOOR, JALAN SULTANAH SAMBUNGAN,
05250 ALOR SETAR, KEDAH.

This is the True and Correct Translation of the Document produced in Serial No. X 603

Sworn Interpreter
High Court,
Alor Setar.
KEDAH
MALAYSIA

DETAILS OF PRODUCT:

Name	:	**GANODERMA CAPSULE**
Name Of Producer	:	**GANO EXCEL ENTERPRISE SDN.BHD.**
Address Of Producer	:	**92-A, LOT 92, MERGONG INDUSTRIAL BARRAGE AREA, PHASE 2B, MERGONG, ALOR SETAR, KEDAH.**
License No.	:	–

The above product is being registered according to the following requirements:

ALL REQUIREMENTS WHICH HAS BEEN APPROVED BY THE CONTROL OF DRUG AUTHORITY.

Period of this registration is from **01st October, 1996 to 01st October, 2001.**

Signed.
TAN SRI (DR.) ABU BAKAR BIN DATO' SULEIMAN
Chairman
Control Of Drug Authority

Previous Registration No. :
Date Issued :

Form 2

CONTROL OF DRUG AND COSMETICS REGULATIONS 1984
(Regulation 12 (1)

DRUG CONTROL AUTHORITY
MINISTRY OF HEALTH MALAYSIA

NO.000691

MANUFACTURER'S LICENCE

LICENCE NO. MALLP20000789

This licence authorises **Gano Excel Enterprise Sdn. Bhd. (Ooi Kheng Seng)** of **Plot 92, Kaw. Perush. Mergong Barrage, Fasa 2B, Mergong 05150 Alor Setar,Kedah.** to manufacture the products listed on the reverse of this licence at the manufacturing premise mentioned below and to sell by wholesale or supply the said products.

Name of manufacturing premise **Gano Excel Enterprise Sdn. Bhd.**
Address **Plot 92, Kaw. Perusahaan Mergong Barrage, Fasa 2B, Mergong 05150 Alor Setar,Kedah.**

The licence is subject to the following conditions:

FOR PRODUCTS TO WHICH THESE REGULATIONS APPLY, THE HOLDER OF THIS LICENCE IS ALLOWED TO MANUFACTURE ONLY THE REGISTERED PRODUCTS PRINTED/LISTED IN THE ENCLOSED LIST.

Store:N0.3, Susuran Shahab,Shahab Perdana,Jalan Sultanah Sambungan, Alor Setar.

(Continued on other sheet attached to this licence*)

This licence is valid from 01 January 2001
to 31 December 2001

Date 24 October 2000

CONDITIONS FOR LICENCE

This licence can be withdrawn at anytime when the premise of business is deemed unsuitable in terms of location,facilities, hygeine,maintenance,records keeping and others.

.....
Chairman,
Drug Control Authority

*Delete where not applicable

Previous licence No.....
Date of issue .....

This is the True and [illegible]
Translation of the [illegible]
produced [illegible] 21/07

NATIONAL PHARMACEUTICAL CONTROL BUREAU

CONTROL OF DRUG AND COSMETICS REGULATIONS 1984
REGULATION 12 (1)
DRUG CONTROL AUTHORITY
MINISTRY OF HEALTH MALAYSIA
PRODUCTS LIST OF MANUFACTURER'S LICENCE

cence No. : MALLP20000789 Name of Manufacturer : GANO EXCEL ENTERPRISE S/B , KEDAH
ate of Issue Of List : 16/11/2000
cence Valid From : 01/01/2001 Hingga : 31/12/2001

o.	Name Of Products	Registration No.	Registration Duration
ass : T			
	EXCELLIUM CAPSULE 425MG	MAL19961983T	01/10/1996-01/10/2001
	GANO GARCINIA CAPSULES 410MG	MAL19990448T	25/02/1999-25/02/2004
	GANODERMA CAPSULES	MAL19961984T	01/10/1996-01/10/2001
	SAKANNO(GANO TONGKAT ALI)CAPSULES	MAL19992490T	30/09/1999-30/09/2004

Items Only)

This is the True and Correct Translation of the Document produced to Serial No 22/01

Sworn Interpreter
High Court,
Alor Setar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: November 11, 2003

From: Interdisciplinary Scientist/Pharmacist , Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: ***Ganoderma lucidum*** **Mushroom Extract**
Firm: Gano Excel (U.S.A.) Inc.

Date Received by FDA: 1/13/03

90-Day Date: 4/13/03

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Gloria Cheng for
Catalina Hachmeister

P drive/ NDI/ NDI File Closeout/DDSP SOP closeout process...