



**Memorandum**

Date: **FEB 06 2004** 6254 '04 FEB 10 11:08  
From: Interdisciplinary Scientist/Botanist, Division of Dietary Supplement Programs,  
Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810  
Subject: 75-Day Pre-market Notification of New Dietary Ingredients  
To: Dockets Management Branch, HFA-305

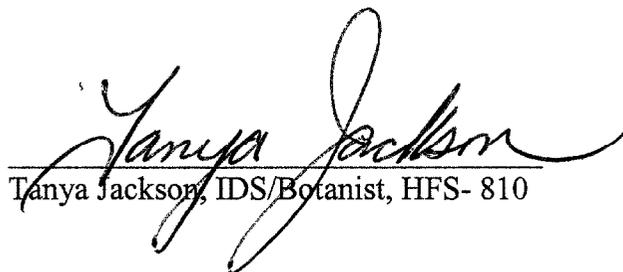
Subject of the Notification: "Chin Shu Tin Foi Chun Dan"

Firm: New Century Company

Date Received by FDA: 7/22/03

90-Day Date: 10/20/03

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day pre-market 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.

  
Tanya Jackson, IDS/Botanist, HFS- 810

Attachments

955-0316

RPT205



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, Maryland 20740

OCT - 2 2003

Mr. David Hsu, President  
New Century Company  
3392 Falcon Ridge Road  
Diamond Bar, California 91765

Dear Mr. Hsu:

This is to inform you that the notification, dated July 13, 2003, that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on July 22, 2003. Your initial notification, dated July 13, 2003, was amended on July 22, 2003 and on August 14, 2003. Your notification concerns dried orange fruit, tangerine peel, and licorice root powder as the substances that you intend to market in your the dietary supplement product "Chin Shu Tin Foi Chun Dan".

Your notification states that the dietary supplement, "Chin Shu Tin Foi Chun Dan", will be marketed in dried powder packs; each pack is to be dissolved in a bottle of water. The amount of the new dietary ingredients per serving (3 packs) is:

0.35 g	Dried Orange fruit
0.15 g	Tangerine Peel
0.10 g	Licorice Root
0.60 g	Total

According to the notification, the recommended intake is 3 packs per day and the duration of use of the product is 1 year.

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.

It is unclear which components of the dietary supplement, "Chin Shu Tin Foi Chun Dan" to be considered as new dietary ingredients. The amendments dated July 22, 2003 and August 14, 2003 clearly state that there are no new dietary ingredients in your dietary supplement product called "Chin Shu Tin Foi Chun Dan".

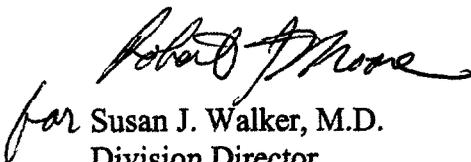
It is unclear which specific species of plants are contained in your dietary supplement "Chin Shu Tin Foi Chun Dan". The notification fails to identify the botanical material, including full Latin binomial name with author citation for each botanical in your dietary supplement product called "Chin Shu Tin Foi Chun Dan". In addition, your notification did not identify the specific physical form of the ingredients in your dietary supplement product called "Chin Shu Tin Foi Chun Dan". For example, is "Chin Shu Tin Foi Chun Dan" made from dried plant materials which have been milled and powdered or from plant extracts which have been concentrated into a powder?

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that dried orange fruit, tangerine peel, and licorice root powder in the dietary supplement product "Chin Shu Tin Foi Chun Dan", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains 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).

Your notification will be kept confidential for 90 days after the filing date of July 22, 2003. After the 90 day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

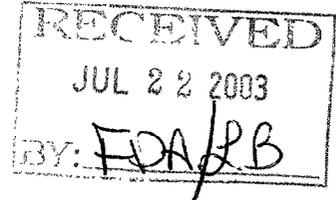
Sincerely yours,



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

**NEW CENTURY COMPANY**  
**3392 Falcon Ridge Rd., Diamond Bar, CA 91765 U.S.A.**  
**Tel: (909) 861-7575 Fax: (909) 396-8706**

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling and Dietary Supplement  
Center for Food Safety and Applied Nutrition  
FDA  
5100 Paint Branch Rd.  
College Park, MD 20740-3835



July 13, 2003

**RE: 75 DAYS PRE-MARKET NOTIFICATION LETTER FOR STATEMENT ON  
DIETARY SUPPLEMENT – Chin Shu Tin Foi Chun Dan**

To whom it may concern,

As the consultant for Sumay Inc., I am sending you our application for 75 days pre-market notification for “Chin Shu Tin Foi Chun Dan” (a dietary supplement product) per Section 413 (a)(2) of the Federal Food, Drug, Cosmetic Act.

I am attaching the literature to show the safety for human consumption for the new dietary supplement ingredients in “Chin Shu Tin Foi Chun Dan (The printed information on the referenced information are stapled together). We feel we have done our best to assure you the food safety of “Chin Shu Tin Foi Chun Dan” for the intended use. About the Structure / functional claim, Please advise a best option for us.

Please inform me if there is/are any other requirements or amendments needed for the application.

Best Regards,

A handwritten signature in cursive script that reads "David Hsu".

David Hsu,  
President

85152

**Sumay Inc.**  
**1108 W. Valley Blvd., #4160**  
**Alhambra, CA 91803**  
**Tel: (626) 826-7989 Fax: (626) 280-3637**

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling and Dietary Supplement  
Center for Food Safety and Applied Nutrition  
FDA  
5100 Paint Branch Rd.  
College Park, MD 20740-3835 July 12, 2003

**RE: 75 DAYS PRE-MARKET NOTIFICATION LETTER FOR  
STATEMENT ON DIETARY SUPPLEMENT**

Dear FDA officers:

Per Code of Federal Regulation, Volume 21, part 101.93 (Section 413 (a)(2) of the Federal Food, Drug, Cosmetic Act), we are enclosing all the required documents for the filing of the pre-market notification on our new upcoming herbal product – “Chin Shu Tin Foi Chun Dan”.

**1. Statement of Purpose**

This is a letter to provide notification of a statement of nutritional support, including the ingredient statement, supplement fact, new dietary supplement ingredient usage and safety data, the text for Structure / Function statement, finished product formulas, and clinical trial report.

**Company Information**

Sumay Inc.  
1108 W. Valley Blvd., #4160, Alhambra, CA 91803  
Tel: (626) 826-7989 Fax: (626) 280-3637

**2. Co-packing manufacturer for “Chin Shu Tin Foi Chun Dan”:**

King Sau Tong Chin Shu Tin Drug Factory in Hong Kong

**3. FDA Consultant information:**

David Hsu  
New Century Company  
3392 Falcon Ridge Rd.  
Diamond Bar, CA 91765  
Tel: (909) 861-7575, Fax: (909) 396-8706

**5. Product identification:**

The trade name of the product: Chin Shu Tin Foi Chun Dan

The common and usual name for the product:

Healthy and Tranquility herb (Foi Chun Dan)

The label will reads like this:

**6. Ingredient Statement:**

Dried orange fruit, tangerine peel, and licorice root.

**7. Supplement facts:**

Serving Size : 3 small packs per day @ 0.2 g powder per pack  
Amount per serving : 0.6 g powder per serving (3 packs).  
Serving per container : To be determined.

FAX To: Vicki Lutwak.

Total pages: 2

From: D. Hsu

New Century Company  
3392 Falcon Ridge Rd.  
Diamond Bar, CA 91765

Tel: (909) 861-7575, Fax: (909) 396-8706

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling and Dietary Supplement  
FDA  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

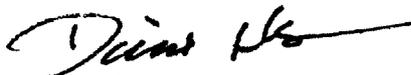
Dear Vicki,

July 21, 2003

Per our telephone discussion today, I am faxing you one amended page on our recent submission of pre-market notification on the dietary supplement product – "Chin Shu Tin Foi Chun Dan" for Sumay Inc.

Please inform me for any questions. Thanks!

Sincerely



David Hsu

Maximum dosage: 3 packs per day  
 Duration of product use : 1 year.

### 8. Formula and Intended Use:

	<u>Amt per serving, % Daily value</u>	
Dried orange fruit	0.35 g	*
Tangerine peel	0.15 g	*
Licorice root powder	0.10 g	*
Total	0.60 g	

- \* Not established
- \*\* All the above are in a powder mix, consumer dissolves the bottle in a bottle of water for consumption.

### 9. The text for Structure / Function statement

This formula helps your muscle health.

This statement has not been evaluated by FDA, this product is not intended to diagnose, treat, cure, and prevent any disease.

### 10. New Dietary supplement ingredients in “Chin Shu Tin Foi Chun Dan”

- None

**Sumay Inc.**  
**1108 W. Valley Blvd., #4160**  
**Alhambra, CA 91803**  
**Tel: (626) 826-7989 Fax: (626) 280-3637**

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling and Dietary Supplement  
Center for Food Safety and Applied Nutrition  
FDA  
5100 Paint Branch Rd.  
College Park, MD 20740-3835                      July 12, 2003

**RE: 75 DAYS PRE-MARKET NOTIFICATION LETTER FOR  
STATEMENT ON DIETARY SUPPLEMENT**

Dear FDA officers:

Per Code of Federal Regulation, Volume 21, part 101.93 (Section 413 (a)(2) of the Federal Food, Drug, Cosmetic Act), we are enclosing all the required documents for the filing of the pre-market notification on our new upcoming herbal product – “Chin Shu Tin Foi Chun Dan”.

**1. Statement of Purpose**

This is a letter to provide notification of a statement of nutritional support, including the ingredient statement, supplement fact, new dietary supplement ingredient usage and safety data, the text for Structure / Function statement, finished product formulas, and clinical trial report.

**Company Information**

Sumay Inc.  
1108 W. Valley Blvd., #4160, Alhambra, CA 91803  
Tel: (626) 826-7989 Fax: (626) 280-3637

**2. Co-packing manufacturer for “Chin Shu Tin Foi Chun Dan”:**

King Sau Tong Chin Shu Tin Drug Factory in Hong Kong

**3. FDA Consultant information:**

David Hsu  
New Century Company  
3392 Falcon Ridge Rd.  
Diamond Bar, CA 91765  
Tel: (909) 861-7575, Fax: (909) 396-8706

**5. Product identification:**

The trade name of the product: Chin Shu Tin Foi Chun Dan

The common and usual name for the product:

Healthy and Tranquility herb (Foi Chun Dan)

The label will reads like this:

**6. Ingredient Statement:**

Dried orange fruit, tangerine peel, and licorice root.

**7. Supplement facts:**

Serving Size : 3 small packs per day @ 0.2 g powder per pack  
Amount per serving : 0.6 g powder per serving (3 packs).  
Serving per container : To be determined.

**8. Formula and Intended Use:**

	<u>Amt per serving, %Daily Value</u>	
Dried orange fruit,	0.35 g	*
tangerine peel	0.15 g	*
licorice root	0.10 g	*
Total	0.60 g	

\* NOT ESTABLISHED \*\*All above ingredient are in grounded powder form, the consumer dissolves the powder in a bottle of water and drink it.

**8. The text for Structure / Function statement:**

This formula helps you to relieve the muscle pain.

This statement has not been evaluated by the FDA, this product is not intended to diagnose, treat, cure or prevent any disease.

**9. New dietary supplement ingredients in "Eighteen Buddha Ta Da Wan":**

---

Common Name	Latin binomial name
Dried whole orange	Citrus aurantium
Tangerine peel	Citrus reticulata var. tangerine
Licorice root	Glycyrrhiza glabra
All sourced from China	

---

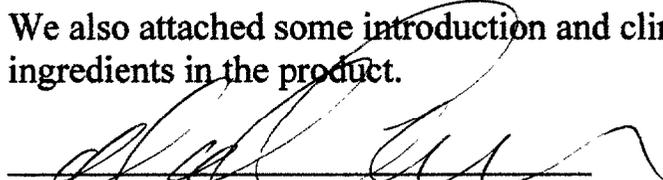
See Fax e amended Page

**10. Percentage of main active ingredient in the finished product –  
100%**

We appoint Mr. David Hsu as our FDA regulation representative in U. S., for any future correspondence, please contact him, his address and contact no. are:

New Century Company  
3392 Falcon Ridge Rd.  
Diamond Bar, CA 91765  
Tel: (909) 861-7575

We also attached some introduction and clinical test literature on the active ingredients in the product.



---

Manuel Chau, General Manager  
Sumay Inc.