



Memorandum

Date
From Acting Director, Division of Programs and Enforcement Policy
Office of Special Nutritionals, HFS-455
Subject 75-Day Premarket Notification for New Dietary Ingredients
To Dockets Management Branch, HFA-305

New Dietary Ingredient: Lo Han Kuo
Firm: Herba Swy Laboratories, Inc.
Date Received by FDA: March 4, 1996
90-Day Date: June 2, 1996

In accordance with the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 after June 2, 1996.

Sincerely yours,

John W. Gordon
Acting Director
Division of Programs
and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Attachment

96 MAR 17 PM 9:26

95S-0316

RPT 3



HerbaSwy™ Laboratories, Inc.

Division of St. John Enterprises & Lip Win Company

RECEIVED BY THE OFFICE OF SPECIAL NUTRITIONALS, HHS-450

'96 MAR -4 P9647 ~~CONFIDENTIAL~~ :33

February 28, 1996
The Secretary
Office of Special Nutritionals
Food and Drug Administration
200 C Street, South West
Washington, DC 20204

Re: Marketing dietary ingredients under
Supplement Health and Education Act.

Attention: Margaret C. Binzer

HerbaSwy Laboratories is requesting marketing clearance for its **Lo Han Kuo** (a Chinese edible herb) extract. The premarket notification information required by FDA's Office of Special Nutritionals is as follows:

- a. Classification name: Natural Cucurbitaceae Fruit Extract
Common/Usual Name: Lo Han Kuo Extract
Proprietary Name: Fruit Extract
- b. Classification: Dietary supplements and their ingredients are governed and regulated under the Dietary Supplement Health and Education Act. Pursuant to Section 8 of the Act such dietary supplements must reasonably be expected to be safe. In consideration of the provisions of this new legislation, HerbaSwy desires to import Natural Cucurbitaceae Fruit Extract for use as a dietary ingredient in dietary supplements and as a standardized dietary supplement product. Extracts and the dried form of **Lo Han Kuo** have been in the US food market as an edible fruit and instant beverage ("**Lo-Han-Kuo Chongji**", see label of product attached hereto as Exhibit 1) for decades. **Lo Han Kuo** and its extracts have been and are reasonably expected to be safe.
- c. Label/Labeling/Advertisements: Draft copies of the package labeling and promotional material for Natural Cucurbitaceae Fruit Extract as well as a list of Scientific Publications are enclosed as Exhibit 2.

We would appreciate your earliest attention to this submission. The Natural Cucurbitaceae Fruit Extract will be displayed at a trade show in the middle of March, but will not be offered for sale until we receive FDA clearance of our submission or upon the expiration of 75 days from this submission.

Sincerely yours,

Enclosures

James Zhou, Ph. D.
VP/Marketing & Business Development

RECEIVED BY THE OFFICE OF SPECIAL NUTRITIONALS, HHS-450
MAR -4 P9647

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Exhibit 1



羅漢果沖劑

一打庄
ONE DOZEN
淨重 6 安士

LO-HAN-KUO BEVERAGE

成份(甜度): 羅漢果95% 優質蔗糖5%

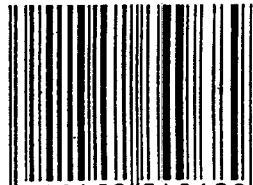
CONSTITUENTS (SWEET)

LO HAN KUO (FRUCTUS MOMORDICAE) 95%

EXCELLENT QUALITY CANE SUGAR 5%

NET WT: 6 OZ. (170 GM)

PRODUCT OF CHINA



羅漢果沖劑

LO-HAN-KUO BEVERAGE

用法用量: 用沸開水100毫升沖化後飲服, 每天2-3次, 每次一塊。

DOSAGE: TO BE TAKEN AFTER HAVING DISSOLVED ONE PIECE OF THE CUBE WITH 100 CC. OF BOILING WATER. ONE PIECE FOR EACH TIME AND 2-3 TIMES FOR EACH DAY

Exhibit 2

CONFIDENTIAL

is a proprietary extract from fruit in Cucurbitaceae subfamily, the plant *Siraitia grosvenorii* S., also called **Lo Han Kuo**, *Thladiantha grosvenorii* S. C. Jeffrey, *Fructus Momordicae*, or *Momordica grosvenori*, and is the trade-mark of **HerbaSwy™ Laboratories**, Division of St. John Enterprises and TripWin Company, P.O. Box 26454, West Haven, CT 06516-0944.

HERBASWY™ LABORATORIES is the only supplier of Cucurbitaceae Fruit Extract to DIETARY SUPPLEMENT INDUSTRY.

Cucurbitaceae fruit is a vine native to the People's Republic of China, called **Lo Han Kuo** in China; and **Rakanka** in Japan. **Lo Han Kuo** is an edible fruit described as having intensely sweet taste and has been used as tea for thousands of years in China as a household herbal remedy for lung congestions, colds, sore throats. The tea of **Lo Han Kuo** has been believed to cleanse and release stomach and intestinal troubles. In addition to its herbal medicinal benefits, the **natural non-caloric sweetness** of this plant has made it further expand in lots of herbal remedies. The sweetness has been mainly attributed to the sweet saponins and mogrosides.

Extracts and the dried form of **Lo Han Kuo** have been in the US food market as edible fruit and instant beverage ("**Lo-Han-Kuo Chongji**") for decades. The extract has been used in Japan as natural sweetener for years. **Lo Han Kuo** and its extracts have been proved safe by millions of consumers in history. All conventional **Lo Han Kuo** extracts in the market contain astringent flavor that has limited their value. **HerbaSwy™ Laboratories** has developed a proprietary preparation technology to eliminate unpleasant flavor and produce tasty Natural Cucurbitaceae Fruit Extracts that will be provided as a trade-mark of **HerbaSwy™ Laboratories**, West Haven, CT.

Natural Cucurbitaceae Fruit Extracts.

Form:

Grade:

*Recommended Levels of Use in A 16 FL OZ Volume:

60-300 mg

B L A N K P A G E

(INFORMATION CONTAINED ON PAGE
NOT CONSIDERED RELEASABLE UNDER FOI)

Scientific Publications

Cucurbitaceae Fruit & Its Extract

Swingle, W.T. , *Momordica grosvenorii* sp.nov. "The source of the Chinese Lo Han Kuo." *Journal of the Arnold Arboretum* 22, 197-205 (1941).

Klein, G.E. et al.; "Intense Sweetener from Luo Han Kuo (*Momordica grosvenorii*"); *Experientia*; vol. 31, No. 5; pp. 533-534 (May 15, 1975).

Jiangsu New Medical Collage, *Zhongyao Dachidian* (Encyclopedia of Traditional Chinese Medicine), People's Publishing Company, Shanghai, pp. 1356-1357 (1977).

Takemoto et al., "Studies on the constituents of fructus *Momordicae*. I. On the sweet principle", *Yakugaku Zasshi-Journal of the Pharmaceutical Society of Japan*. 103 (11): 1151-4 (Nov., 1983).

Takemoto et al., "Studies on the constituents of fructus *Momordicae*. II. Structure of sapogenin", *Journal of Pharmaceutical Society of Japan*. 103(11):1155-66 (Nov, 1983).

Takemoto et al., "Studies on the constituents of fructus *Momordicae*. III. Structure of mogrosides". *Journal of the Pharmaceutical Society of Japan*. 103(11):1167-73 (Nov, 1983).

Anonymous, "High sweetening agents. Market size 11 billion yen. Stevia and aspartame are main products." *Food Chemicals* (Japan) 10, 12-25 (1985).

Makapugay et al., "High-Performance Liquid Chromatographic Analysis of the Major Sweet Principle of Luo Han Kuo Fruits", *J. Agric. Food Chem.* Vol. 33, pp. 348-350 (1985).

Kasai et al., "Sweet Cucurbitane Glycosides from Fruits of *Siraitia siamensis* (chi-zi luo-han-guo), a Chinese Folk Medicine", *Agric. Biol. Chem.*, Vol. 53, No. 12, pp. 3347-3349 (1989).

Raof a. Hussain et al. "Plant -derived sweetening agents: saccharide and polyol constituents of some sweet-tasting plants", *Journal of Ethnopharmacology*, 28, 103-115 (1990).

Matsumoto et al., "Minor Cucurbitane-Glycosides from Fruits of *Siraitia grosvenori* (Cucurbitaceae)", *Chem. Pharm. Bull.*, vol. 38, No. 7, pp. 2030-2032 (1990).

Sumitani et al., "FPD-GC Determination of s-Methylmethioninesulfonium in Satsuma Mandarin Juice", *Agric. Biol. Chem.* vol. 55, No. 11, pp. 2899-2900 (1991).