



Memorandum

Date: MAR 03 2004

From: 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: Neokimchi A

Firm: Neo Kim Chi Inc.

Date Received by FDA: Oct. 30, 2003

90-Day Date: Jan. 28, 2004

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.

Janya G. Jackson Ph.D

955-0316

RPT 2/6



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Mr. Young Kang, President
Neo Kim Chi Inc.
1113 Andrea Drive
San Jose, CA 95117, USA

Dear Mr. Kang:

This is to inform you that the notification, dated October 21, 2003, 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 received by the Food and Drug Administration (FDA) on October 30, 2003. Your notification concerns a substance called "NeoKimchi A" which you describe as a mixture of freeze-dried and powdered kimchi with lactobacillus (Leuconostoc citreum) and ginseng in a 3:2:5 ratio.

According to the notification, you state that the substance "NeoKimchi A" will be sold in capsules which contain 150 mg of freeze-dried kimchi. You recommend 6 capsules/day for a total daily intake of 900 mg of freeze-dried kimchi.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing 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 considered 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.

FDA has carefully evaluated 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 NeoKimchi A will reasonably be expected to be safe.

The notification fails to identify the Latin binomial names including the author of the new dietary ingredient(s) in "NeoKimchi A" as required for any herb or other botanical by Federal regulations found in 21 CFR 190.6(b)(2). Since the notification did not include the Latin binominal names of the components contained in "NeoKimchi A", FDA cannot adequately identify "NeoKimchi A", the intended article of commerce. Moreover, your notification does not contain any information regarding the history of use of your product "NeoKimchi A" nor safety information regarding "NeoKimchi A."

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the NeoKimchi A product, 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 October 30, 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,



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

Date: 10/21/2003

To: **Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820)**
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

Subject: Premarket Notification for a New Dietary Ingredient-NeoKimchi A

P.B./FDA

Dear FDA Administration:

Pursuant to 21 CFR Section 190.6 and 21 USC 350b of the Dietary Supplement Health and Education Act of 1994, requirement for premarket notification for a new dietary ingredient, Neo Kim Chi Inc. wishes to notify the Food and Drug Administration that it will market the NeoKimchi A product as a dietary supplement.

Attached please find the notification letter, the summary, and report of NeoKimchi A, which establish that this dietary ingredient, when used under the recommended conditions, is reasonably expected to be safe.

Respectively,

Young Kang
President
Neo Kim Chi Inc.
1113 Andrea Drive
San Jose, CA 95117, USA
Tel : 1-408-261-0756
Fax : 1-408-516-9822
Mobile : 1-408-828-2964
E-mail : YKANG22@AOL.COM

PREMARKET NOTIFICATION

Freeze-Dried Kimchi (NeoKimchi)

1. The name and address of the distributor of the new dietary ingredient:

Neo Kim Chi Inc.
1113 Andrea Drive
San Jose, CA 95117, USA
Tel : 1-408-261-0756
Fax : 1-408-516-9822
Mobile : 1-408-828-2964
E-mail : YKANG22@AOL.COM

2. Name of the new dietary ingredient:
NeoKimchi: freeze-dried kimchi

3. Description of dietary supplements that contain new dietary ingredient:
NeoKimchi A: a mixture of freeze-dried and powdered kimchi with lactobacillus (*Leuconostoc citreum*) and ginseng in a 3:2:5 ratio.

3 gm of NeoKimchi A: recommended dose of dietary supplement per day, equivalent to 900 mg freeze-dried kimchi.

4. History of use and evidence of safety:

Kimchi has been consumed in Korea for more than 500 years as an ordinary food. It is a staple food in Korea that almost every person eats at almost every meal. In addition, people in many other countries, including the United States, have consumed kimchi for a long time. Recent studies provide evidence supporting that kimchi is an excellent food beneficial to human health. Kimchi has beneficial effects in weightloss, prevents cancer, prevents heart disease, and more.

Typically, 100 to 200 gm of kimchi is consumed per day per person. This is equivalent to 6 to 12 gm of freeze-dried kimchi. One capsule of NeoKimchi A contains 150 mg of freeze-dried kimchi. The recommended daily dose of the new dietary supplement NeoKimchi A, 6 capsules, contains 900 mg freeze-dried kimchi. This amount is equivalent to 15 gm regular undried kimchi, far less than the typical amount of kimchi

consumed daily. Since kimchi has a long history of use as a regular food, it is safe for long-term use. The concern of kimchi is over-ripening upon long-term storage. This over-ripening of kimchi is due to continuing growth of bacteria and fermentation. By freeze-drying and powdering, Neo Kim Chi Inc. intends to make NeoKimchi A into a form that can be stored for an extended period of time on shelves, and is easy to consume. Freeze-drying is the choice of food processing methods to preserve food without changing the chemical nature. Therefore, the freeze-dried kimchi can be stored for a long time without changes of a chemical nature occurring.

Based on the information summarized above, we have concluded that the dietary supplement containing this new dietary ingredient, when used under the conditions recommended in the labeling of the dietary supplement, will be reasonably safe.

Summary and Report of NeoKimchi

Kimchi, a Korean traditional food made of cabbages and radish by fermentation, has been consumed in Korea for a very long time and is still one of the major foods. Recently, kimchi has been the subject of a great attention due to the discovery that it has many known and unknown ingredients beneficial to human health. For example, studies support that hot pepper has the ingredient capsaicin and its analogs that help prevention of obesity and fat reduction. Kimchi has high contents of dietary fiber and vitamins and low content of fat. It has a high number of *Lactobacillus* and *Leuconostoc* known to clean intestines and improve microorganism flora in the intestine. The high content of cellulose fibers in kimchi assists in food digestion and lowers blood cholesterol levels. Garlic, one of the common seasonings in kimchi, is well known to be effective in improving the functions of the heart and bolstering immunity against infection. Taken together, kimchi has an enormous potential as a health food and diet food. The general and detailed description of these health aspects of kimchi are published in numerous articles and scientific papers, and are well described in the official kimchi sites such as <http://kimchi.kfri.re.kr> from the Korea Food Research Institute, and <http://www.kimchi.or.kr>.

Since kimchi is a fermented food and easily over-ripens, it has a relatively short storage life. It has to be consumed when it is properly fermented and fresh. This makes the consumption of kimchi difficult in areas where people are not making and eating them commonly. Therefore, it is necessary to process the kimchi in a stable and long-term

storage form, if we are going to take advantage of its numerous health benefits and promote the food as a health food and diet food.

NeoKimchi A is a form of freeze-dried kimchi that can be stored for an extended period of time on shelves and is easy to consume. In particular, Neo Kim Chi Inc. intends to make NeoKimchi A in a powder form to be packaged in capsules, and sell as a food supplement.

Manufacturing Process

NeoKimchi A will be manufactured as following:

1. Appropriate cultivars of Chinese cabbage, with light-green colored soft leaves and compact structure with no defects, are cut into proper size, and brined in salt solution (8-15%) for 2-7 hours to obtain 2.0-4.0% (w/w) salt content.
2. The cabbages are rinsed several times with fresh water and drained to remove excess water.
3. The seasoning mixture for kimchi is prepared as following: Radish strips (10% of cabbage quantity) and spices including green onion strips (2%), crushed garlic (2%), crushed ginger (1%), hot red pepper powder (2.7%), and other seasonings are blended together.
4. The seasoning mixture is mixed with a culture of *Leuconostoc citreum* containing 10^7 cfu/kg cabbage, from a commercial source, and the whole mixture is evenly blended with pretreated cabbages. The stuffed cabbages are then tightly stacked in a jar and fermented for 3 days at 16-18°C. In the process, adding *Leuconostoc*

citreum, one of the main kimchi *Lactobacillus* species, stimulates ripening of kimchi and helps the kimchi taste fresh and suppresses growth of other bacteria.

5. Whole fermented kimchi is freeze-dried via conventional means and ground into a powder at low temperatures.
6. A blend of kimchi powder:*Leuconostoc*:Korean ginseng in a 3:2:5 ratio for NeoKimchi A is made. Blended powder is then packaged into capsules, 500 mg per capsule. *Leuconostoc* culture and Korean ginseng are to be obtained from a commercial source.

The manufacturing protocols for NeoKimchi have been filed for Korean Patent (Patent Application No. 10-2003-0002206).

The nutritional ingredients of the typical kimchi is as following (from <http://kimchi.kfri.re.kr/2-1-2.htm>)

Nutrients	per 100g of edible portion
Food energy (Kcal)	32
Moisture (g)	88.4
Crude protein (g)	2.0
Crude Lipid (g)	0.6
Total sugar (g)	1.3
Crude fiber (g)	1.2
Crude ash (g)	0.5
Calcium (mg)	45
Phosphorus (mg)	28
Vitamin A (IU)	492
Vitamin B1 (mg)	0.03
Vitamin B2 (mg)	0.06

Niacin (mg)	2.1
Vitamin C (mg)	21

Functions of Kimchi

Diet. Choi et al. reported that rats fed with kimchi-containing high fat food were lower in body fat significantly than rats fed with high fat diet without kimchi (1). In addition, plasma concentrations of triglyceride and cholesterol were also lower in rats fed with kimchi-containing food compared to the controls. This diet effect of kimchi is thought to be due to capsaicin contained in red pepper. An early study showed that dietary supplementation of 0.014% capsaicin in the high fat diets containing 30% lard lowered the perirenal adipose tissue weight and serum triglyceride level significantly, suggesting that capsaicin stimulates lipid mobilization from adipose tissue (2). In recent years, others provided evidence in animal studies that capsaicin and its analogs, found in red pepper, reduced body weight, body fat accumulation, and the levels of serum free fatty acid, total lipids and triglyceride as well as cholesterol in the liver (3,4), supporting the results of earlier studies. Further, in human studies, red pepper and capsaicin and capsaicin analogs were shown to increase body temperature, carbohydrate metabolism, and the oxygen consumption (5,6). The anti-obese effects and metabolism increasing activities of capsaicin and its analogs are from the facts that these compounds act as agonists for vanilloid receptor, and increase plasma levels of catecholamines and stimulates lipogenesis in fat cells (4,5).

Anticancer. The anticancer effect of kimchi was reported that organic solvent extracts from optimally ripen kimchi suppressed tumor growth in vitro and in vivo (7). They showed that the kimchi extracts inhibited the growth of AGS human gastric cancer cells

in vitro (7). Also, it reduced the tumor formation and prolonged the life span of sarcoma-180 cell injected Balb/c mouse significantly (8). In the studies, they suggested that the anticancer effects of kimchi are probably through increasing the hepatic glutathione content and activities of glutathione reductase and glutathione-S-transferase. A separate research supports the anticancer effect of kimchi that the kimchi extracts reduced the number of GST-P+ foci in the liver about 2 to 3 times when animals were treated with diethylnitroamine and D-galactosamine (9), suggesting that kimchi has anti-hepatocarcinogenesis activity. The level of GST, a phase II detoxification enzyme, was increased in these studies also. These anticancer activities of kimchi are believed to be effects of various ingredients of cabbage such as dietary fiber, chlorophyll, and chlorophyllin along with other phytochemicals such as indole-3-carbinol.

Additionally, Kimchi has garlic as an ingredient that is well known to be beneficial to human health in many ways including cancer. The web site www.treelight.com reviews the anticancer activity of garlic (<http://www.treelight.com/health/KimchiHealthy.html>). In brief, garlic is a powerful anti-oxidant and, along with the vinegar and oil, it helps to keep the vegetables in kimchi fresh. Also, garlic is a good natural source of selenium that is a necessary part of glutathione. Glutathione and glutathione-S-transferase (GST) play important roles in detoxification as described above.

Recently, Choi and his colleagues conducted a case-study focused on the association of the dietary factors and gastric cancer (GC) in Korea, and published the results in the journal International Journal of Cancer (10). A significant decrease in GC risk was observed with increased intake of kimchi prepared with cabbage and pepper.