DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date · MAR 16 1999

From Senior Regulatory Scientist, Regulatory Branch, Division of Programs & Enforcement Policy (DPEP), Office of Special Nutritionals, HFS-456

Subject 75-day Premarket Notification for New Dietary Ingredient

To Dockets Management Branch, HFA-305

New Dietary Ingredients:	Chicken Sternal Cartilage
Firm:	Chick Cart, Inc.
Date Received by FDA:	March 15, 1999
90-day Date:	June 11, 1999

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 11, 1999.

Robert J. Moore, Ph.D.

95S-0316

RPT44

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR 16 1999

Mr. Marvin L. Schilling
Chick Cart, Inc.
P.O. Box 5365
Fort Smith, Arkansas 72913

Dear Mr. Schilling:

This is to notify you that your submission pursuant to section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) dated March 9, 1999, concerning the marketing of a substance that you assert is a new dietary ingredient (i.e., chicken sternal cartilage) was received by the Food and Drug Administration (FDA) on March 15, 1999. Your submission will be kept confidential for 90 days from the date of receipt, and after June 11, 1999, 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,

Robert J. Moore

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Programs and Enforcement Policy
Office of Special Nutritionals

CHICK CART, Inc.
P.O. Box 5365
Fort Smith, AR 72913

March 9, 1999

Office of Special Nutritionals (HFA-450)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street, NW
Washington, D.C. 20204

TO WHOM IT MAY CONCERN:

Please consider the following information as notification of a dietary ingredient:

1. **Manufacturer's Name and Address:**

   Chick Cart, Inc.
   3201 South O Street, #16
   P.O. Box 5365 .
   Fort Smith, AR 72913

2. **Name of dietary ingredient:**

   The name is chicken sternal cartilage.

3. **Description of the dietary supplement that contains the dietary ingredient:**

   THE FOLLOWING SECTION (i) IS TRADE SECRET AND CONFIDENTIAL COMMERCIAL INFORMATION:

   (i) Each capsule of the dietary supplement contains 200mg of chicken sternal cartilage. The cartilage is stabilized with potassium chloride for microbial safety.

   (ii) The recommended dosage is one (1) capsule per day for the first 30 days and if

4. History or Evidence of Safety

THIS SECTION, SECTION 4, IS TRADE SECRET AND CONFIDENTIAL COMMERCIAL INFORMATION:

This dietary supplement has been present in the food supply as an article in food and and can reasonably be expected to be safe as follows:

- Chicken sternal cartilage is found in mechanically separated chicken (MSC) at a rate of 2.3%. MSC is a common ingredient in food formulations and is allowed up to a 100% level in food formulas. At this level, one 2-ounce portion contains 1250mg of chicken sternal cartilage. This article of food delivering 1250mg has no upper limit defined.

- Amino acids are constituents of chicken sternal cartilage and are common to the food supply. This dietary ingredient is not chemically altered as the neutral pH of this supplement provides for chemical stability (1). Also, chemical alteration of this ingredient is inhibited by the use of a chloride salt, as chloride salts are known to be a structure stabilizer (2).

Regarding microbial safety, the two major hurdles include reduced water activity along with high salt concentration in the formulation, described as follows:

- The water activity is reduced to less than 0.6 Aw. The marker used for pathogenic activity in regards to water activity is *Staphylococcus aureus*. This organism is known to survive better than any other pathogen at reduced water activies. When using salt to reduce water activity, this index is around 0.86 Aw (3). Another citation for the use of water activity in stabilizing this ingredient shows that at a Aw of 0.62, there is no microorganism and spore germination activity (4). Because water activity is known as a strong hurdle regarding microbial safety, the government is specifying regulations regarding Aw levels (5). Further, there are reports that show that foods containing 15% salt or greater are shelf stable (6).

- The salt concentration is 50%, causing hypertonic and plasmolysis conditions that cause microorganism inhibition and death. The inhibitory effects of salt are not dependent on pH, as are some other preservatives. Most bacteria are inhibited by 20% or less of salt (7). Potassium chloride has been present in the food supply as an article in food and can reasonably be expected to be safe. According to government guidelines, potassium chloride (a common sodium chloride substitute as it is chemically similar to sodium chloride) delivers 51.9% potassium and the government recommendation for potassium is 3500mg in a daily 2000-calorie diet. One capsule of this dietary supplement delivers 3% daily value in this regard.

Chick Cart, Inc. is licensed to manufacture this dietary ingredient by U.S. Patent Nos. 5,529,786; 5,637,321; 5,645,851; and 5,750,144. Because the last three patents are a continuation in part of patent number 5,529,786, we have only enclosed the last patent issued, 5,750,144, dated May 12, 1998.

If more information is needed, please let us know.

5. Signature of the manufacturer of this dietary supplement.

CHICK CART, INC.

BY: _____
MARVIN L. SCHILLING

ITS: PRESIDENT

MLS/rdf

Attachments (8)

REFERENCES

1. Damodaran, S. Amino Acids, Peptides and Proteins. In "Food Chemistry", ed. Fennema, O. W., 3rd Edition, p. 362. Marcel Dekker, Inc., NY, NY.

2. Damodaran, S. Amino Acids, Peptides and Proteins. In "Food Chemistry", ed. Fennema, O. W., 3rd Edition, p. 364. Marcel Dekker, Inc., NY, NY.

3. Fennema, O. W. Water and Ice. In "Food Chemistry", ed. Fennema, O. W., 3rd Edition, p. 43. Marcel Dekker, Inc., NY, NY.

4. Mujumdar, A. S. Drying Fundamentals. In "Industrial Drying of Foods," ed. Baker, C. G. J., 1st Edition. p. 20. Chapman & Hall, London, UK.

5. Troller, J. A. and Scott, V. N. Measurement of Water Activity (Aw) and Acidity. In "Compendium of Methods for the Microbiological Examination of Foods," eds. Vanderzant, C. and Splittstoesser, D. F., 3rd Edition, Compiled by the APHA Technical Committee on Microbiological Methods for Foods, p. 138. American Public Health Association, Washington, D.C..

6. Fennema, O. W. Water and Ice. In "Food Chemistry", ed. Fennema, O. W., 3rd Edition, p. 53. Marcel Dekker, Inc., NY, NY.

7. Jay, J. M. "Modern Food Microbiology," 5th Edition. p. 285. Chapman & Hall, NY, NY.

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