Date: AUG 9 2006

From: Consumer Safety Officer, 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: Extramel-cantaloupe melon extract

Firm: Seppic, Inc.

Date Received by FDA: May 11, 2006

90-Day Date: August 9, 2006

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.

__Victoria Lutwak__
Mr. Robert McKay, Vice President  
Seppic, Inc.  
30 Two Bridges Road, Suite 210  
Fairfield, New Jersey 07004

Dear Mr. McKay:

This is to inform you that the notification, dated April 28, 2006, 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 May 11, 2006. Additional information incorporated into a revised notice, dated June 7, 2006, was received on June 14, 2006. Your notification concerned the substance that you identified as “Extramel,” cantaloupe melon extract, Cucumis Melo L, that you intend to market as a new dietary ingredient.

Your notification states that you intend to market a product consisting of a powder. Under conditions of use stated in your notice you state: "10 mg of “Extramel” is the recommended daily dose, equivalent to 142 I.U. of antioxidant enzymes (superoxide dismutase and catalase) and 1.8 μg of other antioxidants."

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 considered the information in your submission and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement
containing “Extramel” will reasonably be expected to be safe. Your notification did not provide a
description of your extraction process except in very general terms and did not provide details
of the manufacturing process. Additionally, you did not provide a history of use or other safety
about the material that is the subject of the notice, whole cantaloupe including the rind,
establishing that the dietary ingredient, when used under the conditions recommended or
suggested in the labeling of the dietary supplement, will reasonably be expected to be safe.

For the reasons discussed above, the information in your submission does not provide an
adequate basis to conclude that “Extramel” 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 May 11, 2006.
After the 90-day date, the notification will be placed on public display at FDA’s Docket
Management Branch in docket number 9550316. 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) 436-1775.

Sincerely yours,

[Signature]

Linda S. Pellicore, Ph.D.
Supervisory Team Leader, Senior Toxicologist
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
8 June, 2006
Amending 28 April, 2006

Office of Nutritional Products (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
510 paint Branch Parkway
College Park, MD, 20740-3835

Re : notification of a new dietary ingredient

Pursuant to 21 CFR, Part 190, Subpart B, Sec. 190.6 notification is hereby provided of a new ingredient.

1. Name and complete address of distributor of the new dietary ingredient

SEPPIC Inc.
30 Two Bridges Road
Suite 210
Fairfield, New Jersey, 07004
USA

2. Name of the new dietary ingredient

EXTRAMEL

3. Description of dietary supplements that contain the new dietary ingredient; Level of new dietary ingredient in the dietary supplement.

Cantaloupe melon (Cucumis Melo L.-Carl Linneaus) extract rich in antioxidants. EXTRAMEL is sold in powder form and is recommended as an antioxidant dietary supplement.

Ordinary conditions of use of the supplement

10 mg of Extramel is the recommended daily dose, equivalent to 142 I.U. of antioxidant enzymes (superoxide dismutase and catalase) and 1.8 µg of other antioxidants (as vitamins A, E, C, carotenoids). Due to the fact that the recommend daily dose of EXTRAMEL contains less than a normal daily serving of Cantaloupe, the extract may be considered to be entirely safe.
History of use and evidence of safety

Cantaloupe melon is a widely and commonly consumed fruit either eaten raw or served in deserts such as ice cream, yoghurt, etc. Cantaloupe melons are a rich dietary source of antioxidants as antioxidant enzymes, vitamins and carotenoids.

A quarter of fresh cantaloupe melon contains 142,000 IU of antioxidant enzymes (superoxide dismutase and catalase) and 18 mg of other antioxidants (as vitamins A, E, C, carotenoids).

The recommended daily dose of the new dietary ingredient Extramel cantaloupe melon extract rich in antioxidants contains 142 IU of antioxidant enzymes (superoxide dismutase and catalase) and 1.8 μg of other antioxidants (as vitamins A, E, C, carotenoids), which correspond to a tea spoon of fresh Cantaloupe melon.

To ensure the protection of antioxidant in Extramel, 20% of Cantaloupe melon extract is coated with 80% of hydrogenated palm oil. The palm oil is a common excipient.

The manufacturing process is as follows:
The melons are selected and washed, then crushed, and the pulp is recovered. The juice is clarified, centrifuged and filtered, then concentrated. The result is freeze dried and coated with palm oil as a protective excipient. Rinds, seeds and pulp are not included. No catalysts or other chemicals are added.

An oral toxicity study (rat) is included.

Respectfully submitted,

Robert B. McKay
SENIOR VICE PRESIDENT
Seppic, Inc.
30Two Bridges Rd.
Suite 210
Fairfield, NJ 07004

Enclosure:
Technical data sheet of Extramel
Specifications of Extramel
Certificate of analysis of Extramel
ACUTE ORAL TOXICITY TEST IN THE RAT
SPECIFICATIONS

Product: EXTRAMELO® microgranules
Product code: 11024H
Description: Melon pulp extract coated with vegetal fat matter

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspect</td>
<td>Non soluble microgranules</td>
</tr>
<tr>
<td>Colour</td>
<td>Cream</td>
</tr>
<tr>
<td>Odour</td>
<td>Characteristic</td>
</tr>
<tr>
<td>Dry matter</td>
<td>Min. 95 %</td>
</tr>
<tr>
<td>Proteins</td>
<td>Max. 2 %</td>
</tr>
<tr>
<td>Melon pulp extract</td>
<td>20 %</td>
</tr>
<tr>
<td>Hydrogenated fat matter of vegetal origin</td>
<td>80 %</td>
</tr>
<tr>
<td>Superoxide dismutase activity</td>
<td>14 U/mg</td>
</tr>
<tr>
<td>Conservator</td>
<td>None</td>
</tr>
<tr>
<td>Total germs</td>
<td>Max. 10 000 CFU / g</td>
</tr>
<tr>
<td>Yeast &amp; Mould</td>
<td>Max. 100 CFU / g</td>
</tr>
<tr>
<td>Enterobacteria</td>
<td>Max. 100 CFU / g</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>Absence / g</td>
</tr>
<tr>
<td>Salmonella</td>
<td>Absence / g</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>Absence / g</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Absence / g</td>
</tr>
</tbody>
</table>

(1) SOD activity is measured according to the Oberley and Spitz method 1985 based on the activity of SOD to inhibit the reduction of NBT by O₂⁻ generated by a xanthine/xanthine oxidase system (Δ DO₂⁻ initial = 0,025).
One unit of SOD gives 50 % inhibition of the reduction of NBT.

Packaging: 500g in opaque plastic flacons
Storage: To store in a dark and dry place
Shelflife: 18 months

Product manufactured by BIONOV (France)
**EXTRAMEL®**

**Micro-granules**

**BATCH NUMBER**

*Manufacturing date*

M 03.01

02/2003

**Physical characteristics**

- Aspect
- Color
- Odor

**Physicochemical characteristics**

- Dry matter
- Proteins
  - (BRADFORD method)
- SOD activity (1)
- Preservative

**Microbiological analysis**

- Total germs
- Yeast and mould
- E. Coll
- Salmonella
- Staphylococcus aureus
- Pseudomonas aeruginosa

**Shelf Life / Storage Conditions**

- Shelf Life: 18 months in unopened original packaging.
- Store in a cool, dark and dry place.
- Recommended storage conditions: 68°F (20°C) and 50% Relative Humidity

Date of issue: 30/04/2003

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(1) SOD activity is measured according to the Oberley and Spitz method 1985 based on the activity of SOD to inhibit the reduction of NBT by O2 generated by a xanthine/xanthine oxidase system (Δ DO25 = 0.025). 

One unit of SOD gives 50% inhibition of the reduction of NBT.

GBSA laboratory - University of Montpellier (France)
EXTRAMEL®
microgranules

Antioxidant melon extract

- Source of SOD, a powerful antiradical compound
- Optimal action thanks to a specific coating
- Natural complex of antioxidants
1 - DESCRIPTION

EXTRAMEL® microgranules is a natural melon extract, rich in various antioxidants, including superoxide dismutase. It is obtained by a physical process and protected by a coating of vegetable fat matters (80%).

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<th>Microgranules</th>
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</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Cream</td>
</tr>
<tr>
<td>Taste / Odour</td>
<td>Characteristic</td>
</tr>
</tbody>
</table>

2 - SPECIFICATIONS

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<th>Standards</th>
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</tr>
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<td>Absence / g</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
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</tr>
</tbody>
</table>
3 - ANALYSIS

3.1 - Active ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Results (mg/100g of powder)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOD (activity /mg)</td>
<td></td>
</tr>
<tr>
<td>Catalase (activity / mg)</td>
<td></td>
</tr>
<tr>
<td>Co-enzyme Q10 (/100g)</td>
<td></td>
</tr>
<tr>
<td>Carotenoids (/100g)</td>
<td></td>
</tr>
<tr>
<td>Vitamin A (/100g)</td>
<td></td>
</tr>
<tr>
<td>Vitamin E (/100g)</td>
<td></td>
</tr>
<tr>
<td>Vitamin C (/100g)</td>
<td></td>
</tr>
<tr>
<td>Selenium (/100g)</td>
<td></td>
</tr>
<tr>
<td>Lipoic acid (/100g)</td>
<td></td>
</tr>
<tr>
<td>Glutathione (/100g)</td>
<td></td>
</tr>
</tbody>
</table>

3.2 - Minerals

<table>
<thead>
<tr>
<th></th>
<th>100g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td></td>
</tr>
<tr>
<td>Magnesium</td>
<td></td>
</tr>
<tr>
<td>Sodium</td>
<td></td>
</tr>
<tr>
<td>Potassium</td>
<td></td>
</tr>
</tbody>
</table>

3.3 - Nutritional facts

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein (N x 6.25)</td>
<td>1.8%</td>
</tr>
<tr>
<td>Fat</td>
<td>80%</td>
</tr>
<tr>
<td>Carbohydrate (by subtraction)</td>
<td>15.2%</td>
</tr>
<tr>
<td>Ashes</td>
<td>1.94%</td>
</tr>
<tr>
<td>Recommended daily dosage</td>
<td>10 mg/day</td>
</tr>
</tbody>
</table>
4 - PHYSICAL DATA

Loss on drying
Solubility
Temperature

5 - TOXICOLOGICAL AND REGULATORY DATA

5.1 - Toxicology

Acute dermal test/rabbit
Acute toxicity: LD0 and LD 50 orally/rat

5.2 - Regulatory data

Extract of melon pulp, EXTRAMEL® microgranules is a food derivative product coated with food approved fat matter. It is not an additive and could be use freely in nutraceutical and health food products.

6 - PACKAGING AND STORAGE

Packaging 500 g in opaque plastic flacon
Storage Before opening the packing, store in a dark and dry place
Shelflife 18 months
Transport – labelling Product not under the transport regulations
7 - USES

EXTRAMEL® microgranules is used as a nutritional ingredient for its health benefits in diary products and desserts, cereal based products (biscuits, bars, ...) sport foods and dietary/nutraceutical supplements.

Product manufactured by BIONOV (FRANCE)
Nota

The analytical specifications warranted are only those mentioned on the certificate of analysis supplied with each delivery of the product.

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* SEPPIC being:

and, depending on the country:

SEPPIC S.A.
75, quai d’Orsay
75321 Paris cedex 07
FRANCE
Tel. : +33 (0) 1 40 62 55 55
Fax : +33 (0) 1 40 62 52 53

SEPPIC UK Ltd
50 Salisbury Road
PO Box 338 - Hounslow
TW4 6SH - ENGLAND
Tel. : +44 208 577 8800
Fax : +44 208 570 2106

SEPPIC Italia Srl
Via Quarenghi 27
20151 Milano
ITALY
Tel. : +39 02 38009110
Fax : +39 02 38009140

SEPPIC Inc.
30, Two Bridges Road, suite 210
Fairfield, New Jersey 07004-1530
USA
Tel. : +1 973 882 5597
Fax : +1 973 882 5178

SEPPIC China
Room 510 Jin Tai Building
58 South Mao Ming Road
Shanghai 200020 CHINA
Tel. : +86 (21) 64 66 01 49
Fax : +86 (21) 64 66 11 09

www.seppic.com
Subsidiary of the AIR LIQUIDE group

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