Notification Dossier

Simplified Procedure for substantiated Equivalence

REQUEST FOR SCIENTIFIC EVALUATION OF SUBSTANTIAL EQUIVALENCE FOR NATURIS NON-GM PHYTOSTEROL INTENDED TO BE USED IN PRIOR APPROVED FOOD APPLCIATIONS

February 2007

Applicant Manufacturer

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1. SUMMARY

Under Regulation EC/258/97 on Novel Foods and Novel Food Ingredients, Archer Daniels Midland (ADM) received the approval of the use of its phytosterol product as Novel Food Ingredient under European Commission Decision 2004/333/CE.

Naturis product is extracted from non genetically modified soy bean seeds. It is a mixture of beta-sistosterol, beta-sistostanol, campesterol, stigmasterol and campestanol. The certificates of analysis (appendix A, 1-5) provided demonstrate a composition in sterols in compliance with the commission decision 2004/333/CE.

The manufacturing process of Naturis product is similar to the one described in the ADM Novel Food Application (for sterols from soy bean oil and lesser amount of edible oil).

The Naturis product has minimal contamination and the purity and composition of the presented phytosterol product would be considered safe for human consumption.

The Naturis phytosterol product is intended to be consumed in a manner identical to the ADM product. The labelling of the product will follow the requirement of the relevant commission regulation (608/2004).

This dossier provides evidence to confirm that Naturis' phytosterol product is substantially equivalent to ADM Approval 2004/333/CE.

1. INTRODUCTION AND BASIS FOR THE NOTIFICATION

Regulation (EC) No 258/97 on novel foods and novel food ingredients provides for a simplified procedure for manufacturers to introduce novel food ingredients to market in the EU by making a notification in accordance with Article 5.
Under the same European regulation 258/97 on Novel Foods and Novel Food Ingredients set out rules for authorization of GM food products and other categories of novel foods. Phytosterols fall under the scope of the above mentioned regulation and are identified as "novel" food under article 1.

This procedure is applicable to food ingredients extracted from plants that can be shown to be "substantially equivalent" to an existing or approved novel food ingredient in its composition, nutritional value, metabolic handling, intended uses, safety and levels of undesirable substances.

The applicant and its distributors are requesting that the Advisory Committee on Novel Foods and Processes (ACNFP) to review the information and data provided in this notification and confirm that the novel ingredient proposed as phytosterols acceptably meets the criteria for substantial equivalence.

The first approval for the use of phytosterols as a novel food ingredient was granted to Unilever for the use of phytosterol esters as a novel food ingredient in yellow fat spreads in European Commission Decision 2000/500/EC of 24 July 2000.

In 2004, the Commission issued further Decisions concerning the use of a number of products containing phytosterol ingredients by:

Archer Daniels Midland (2004/333/EC)
Pharmaconsult Oy (2004/334/EC)
Unilever (2004/335/EC)
Teriaka Ltd (2004/336/EC)

Naturis hereby applies for a favourable opinion regarding the substantial equivalence of its phytosterols refered to in Commission Decisions 2000/500/EC and 2004/335/EC, in order to put phytosterols on the market as ingredients for the food applications.

This dossier will demonstrate that Naturis non GM phytosterol product is substantially equivalent within the terms of Article 3 of the EC regulation 258/97
to already approved applications and more specifically the Archer Daniels Midland (ADM) (2004/333/CE). The Naturis product will fall under the scope of class1.1 as defined in the recommendation.

Based on these decisions, Naturis applies for a favourable opinion in order to notify its phytosterol as a novel ingredient in the range of product types into which phytosterols may be added, according to decision 2004/333/CE. The opinion of the Food Standards Agency will be used to support notifications to be made either by Naturis phytosterols the name of the sterols will be GF 95% Non-GMO free Oilseed Phytosterols
on its own name for the benefit of its future customers or to support notifications by its customers. This application is also based on the relevant SCF opinion on the safety of phytosterols and phytosterols esters in relation to the authorisations that we are claiming substantial equivalence.

2. ADMINISTRATIVE INFORMATION

Name of Applicant:

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The supplier of the Naturis product is :

ROBT MORGAN, INC.
PO Box 877
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Name of Ingredient :
Naturis GF 95% Non-GMO free Oilseed Phytosterols

Date of Notification: March 2007

3. NOVEL FOOD NON-GM PHYTOSTEROL

Naturis sterols are manufactured to a “free sterol” product “ isolated from soyabean oil from non-GM plants. The product is not esterfied with vegetable oil so it is a dry, white, free-flowing powder.

According to SCF opinion(11), ADM obtain their sterols from by-products of traditional vegetable oil refining. The source is commonly a blend of crude edible oils, consisting largely of soy bean oil and lesser amounts of other edible oils, e.g. corn, rapeseed and palm oil in varying proportions.

The seeds are procured from the world oil seed supply and some may be derived from genetically modified (GM) plant varieties.

Since the phytosterols are obtained from the seeds of natural origin (from non-genetically modified plants), Naturis’ composition requirements are strict and thus, the source used for the Naturis product is comprised within that described by ADM, demonstrating the substantial equivalence the Naturis’ phytosterol product is soybean derived sterol with beta-sitosterol as main component. Specification sheet and analytical results on sterol composition are given in Appendix A and B.

3.1.1. Sources & manufacturing process

This process is very close to the one described in the SCF Opinion and ADM Novel Food Application:

The crude oil, which is obtained by pressing or solvent extraction, undergoes a series of refining processes to remove solvents, lecithins, free fatty acids, colour bodies, off-odours and off-flavours. In one of these steps, the oil is subjected to steam distillation at reduced pressure (deodorisation) and the resulting distillate contains the sterol fraction. From this fraction, fatty acids, lecithins and other compounds are removed by fractional

distillation, thanolysis/ transesterification, distillation and crystallisation from a heptane solution, and the sterols are further purified by recrystallisation using food grade materials and good manufacturing practices. According to the applicant, the extraction and purification steps are standard methods and similar to the procedures used traditionally by the food industry for the production of plant sterols. Sterol esters are produced from the sterols using food grade vegetable oil-derived fatty acids or triglycerides and applying standard methods for esterification or transesterification commonly used in the fats and oils industry.

Contamination/Purity (Gc-Fid Or Equivalent Method)

These phytosterols are specified according to current food grade requirements in terms of heavy metals and microbiology. The crude sterols used to make this product were manufactured prior to the introduction of Genetically Modified Soybeans and hence can be certified as Non-GMO, A copy of the certification, which will supplied with each batch of GF95% sterols is appended. Sample Lot certification seen in Appendix A shows a GC-FID analyses performed on phytosterols, proving compliance with the legally required purity profile and proving substantial equivalence with the profile of the phytosterols that are approved for the use in fat spreads according to Commission Decision 2000/500/EC.

As the composition data demonstrate, there is essentially the same composition and purity of the constituents in the phytosterols of the subject notification and prior notified substances given in the EU specifications for phytosterols in Table 1 and Appendix B. These product compositions are in general in compliance with the phytosterol profile and purity criteria as required by the latest Decisions of the European Commission and SCF on the use of plant sterols in foods (2004/333- 336/EC and 2004/336/EC). Thus, they are considered to be ‘substantially equivalent’ to the prior authorised phytosterols.

3.1.2. Analytical Determination of Product Composition

The Certificates of Analysis for the analytical data on soyabean oil derived phytosterol product Lot (041806) are in Appendix A and methods of analysis in Appendix C. These data also demonstrate that the composition of this product from the manufacturing process is generally consistent with EU requirements and substantially equivalent to the approved ADM phytosterols that have been the subject of multiple notifications.

3.1.3 Specifications

Phytosterol profile

The sterol profile is defined in annex 2 of decision 2004/333/CE(3) under the following section "Specifications of phytosterols and phytostanols for the addition to foods and food ingredients". To be considered as "substantially equivalent", Naturis product must meet the same requirements. A comparative evaluation of the EU requirements for Naturis and ADM specifications follow:

Naturis produces certified non-GMO free phytosterols derived from vegetable oil. The finished product contains a typical composition of sterols that includes sitostanol, stigmasterol, campesterol, campestanol. brassicasterol and other minor phytosterols. The country of origin is the United States and the sterols are certified non-GMO.

The phytosterols that are the subject of this equivalency assessment are comprised primarily of the sterols mentioned above. Compliance with the specification established in Decision 2004/845/EC indicates there are no concerns related to free phytosterol from non GM soyabean oil.

The novel ingredient is phytosterols and phytosterol esters. The esters are similar to the ingredient used in Unilever's yellow fat spreads that were previously approved under Regulation (EC) No 258/97 on Novel Foods and Food Ingredients.

Table 1.

Composition (with GC-FID or equivalent method)	**Requirements 2004/333/CE ADM**	**Naturis product specifications**
β-sitosterol	≤ 80%	55.7%
B-sitostanol	< 15%	3.69%
campesterol	< 40%	27.79%
campestanol	< 5%	1.40%
stigmasterol	≤ 30%	3.55%
brassicasterol	< 3%	0.00%
other sterols/stanols	< 3%	2.94%
Total sterols	> 94% minimum	95%

Theses analytical results are representative of the quality of the Naturis product.
All the data are in compliance with the requirements demonstrating the equivalence.

According to the new analytical data defined by the commission decision 2004/333/CE(3) the total sterols contain must be superior to 99% only when extracted from sources other than vegetable oil suitable for food: this is not our case, a level of around 95% can be acceptable.

3.1.4. Proposed Novel Food Types & Intake estimates

Yellow fat spreads, milk type products, yoghurt type products and spicy sauces were approved under decision 2004/334. In addition, other applications for milk-based fruit-containing drinks, yoghurt-type products, salad dressings, soya drinks and cheese-type products using the same phytosterol specifications as those for 2004/334 have been approved under decisions 2004/333/EC and 2004/336/EC. Decisions 2004/333-336/EC do not specify the source of the approved phytosterols. Nonetheless, phytosterols used must meet the generalized specifications in Annex 2 of these decisions.

In September 2000, a separate application was made by Novartis (now Forbes Medi-Tech) to allow milk based beverages with added phytosterols to be placed on the market. A decision (2004/845/EC) in accordance with Directive 258/97 was issued on 12 November 2004. The specification for this product differs from the March 2004 decisions (2004/333-336/EC) in that up to 35% ß-sitostanol and campestanol up to 15% were permitted. Based on this decision and the Opinion of the Scientific Committee on Food on Applications for Approval of a Variety of Plant Sterol-Enriched Foods (5 March 2003), the sterol specifications for plant derived phytosterols and phytosterol esters for food addition have been generalized for approval of new applications based on the SCF recommendations. The specification from 2004/845/EC decision to Forbes Medi-Tech that is recommended in the SCF Opinion (5 March 2003) and applicable to further.

The products in each case differ slightly but applications and intake estimates are summarised below as:

- Milk type products, such as semi-skimmed and skimmed milk type products, possibly with addition of fruits and or cereals. The 'milk' type products will be packaged in standard cartons containing 1g free phytosterols per 250 mL serving
- Salad dressings including mayonnaise. These will be packaged in single serving packs containing 1.0 g phytosterols per serving.
- Fermented milk type products such as yoghurts, soya drinks and cheese type products (fat content <12 g per 100 g) where the milk fat and or protein has been partly or fully replaced by vegetable fat or protein. The fermented milk type products will be packaged in individual packs or multipacks. Each serving container will contain 1 g free phytosterols.
- Spicy sauces These will be packaged in single serving packs containing 1.0 g phytosterols per serving.
- Yellow fat spreads as defined by Council Regulation 2991/94 (excluding cooking and frying fats, and spreads based on butter or other animal fat). The yellow fat

spreads will contain 1g (free) phytosterols in 12.5g spread or up to up to 8 % w/w of added phytosterols as currently defined in Commission Decisions 2000/500/EC and 2004/335/EC.

3.1.5. Estimation of Consumer Intake

The applicant will not be involved directly in the addition of plant sterols to foods but will rather supply the product to novel food manufacturers. The addition of substantially equivalent phytosterols to the prior approved food types in the certain amounts will unlikely increase the dietary intake of these ingredients by the consumer. Consumer use will be competitive with products already on the market and therefore only share the existing market with these products. The overall intake of phytosterols by the consumer will not be affected because the Naturis Phytosterol product will act as an alternative non GM consumption within a food type or category and not cumulative. No increase in consumer intake above the current amounts of phytosterols is anticipated as the Naturis product will be added to the same products as those already approved in decision 2004/333. For this reason the daily intake of sterols will not be increased within the European Community population.

3.1.6. Labelling of Novel Foods with Phytosterols

This assessment is supported by the post marketing surveillance conducted by Unilever on the consumer intakes associated with yellow fat spreads containing phytosterols, in accordance with the requirements of Decision 2000/500. A document reporting the findings of this Post Launch Monitoring was submitted to the European Commission (EC) in January 2002. This report concluded that yellow fat spreads containing phytosterol esters were being bought and consumed by the target population, albeit at levels below those originally anticipated. In general, intakes
per household were similar, irrespective of the number of people in the household, indicating that usage was predominately by one person in each household and confirming the pre-market assumptions about the type of consumer that will purchase cholesterol-

lowering products. The yellow fat spread has had a low market share (0.1-2.5%) across most EU yellow fat spread markets. The approved range extensions of other approved novel foods will be targeted at the 'cholesterol concerned' and, due to the cost of phytosterols, will carry premium prices significantly above standard or unfortified products. The proposed and prior approved products are expected to be purchased by a similar target population to the spread, with market shares likely to be less than 1.0% in each category.

Regulation (608/2004/EC) concerning the labelling of foods and food ingredients with added phytosterols, has been in force since April 2004. This requires all foods sold in the EU containing such materials to comply with the labelling requirements below. As a vendor supplying the phytosterols to food processors, DDO Processors, Inc. and its agents will advise the end product novel food manufacturer of the requirements of Regulation 608/2004/EC, Article 2, indicating that they should comply with all labelling, food pack size and serving requirements, namely:

"For labelling purposes, phytosterol shall be designated respectively by the terms 'plant sterol'. Without prejudice to the other requirements of Community or national law concerning the labelling of foods or food ingredients with added phytosterols shall contain the following:

1. In the same field of vision as the name under which the product is sold there shall appear, easily visible and legible, the words; 'with added plant sterols
2. The amount of added phytosterols content (expressed in % or as g of free plant sterols per 100 g or 100 ml of the food) shall be stated on the list of ingredients;
3. There shall be a statement that the product is intended exclusively for people who want to lower their blood cholesterol level;
4. There shall be a statement that patients on cholesterol lowering medication should only consume the product under medical supervision;
5. There shall be an easily visible and legible statement that the product may not be

nutritionally appropriate for pregnant and breastfeeding women and children under the age of five years;
6. Advice shall be included that the product is to be used as part of a balanced and varied diet, including regular consumption of fruit and vegetables
7. In the same field of vision as the particular required under point 3 above, there shall be a statement that the consumption of more than 3 g/day of added plant sterols/plant stanols should be avoided;
8. There shall be a definition of a portion of the food or food ingredient concerned (preferably in g or ml) with a statement of the plant sterol amount that each portion contains."
12 In addition, manufacturers of finished foods will be reminded of the obligation for novel food products to be presented by the novel food supplier in such a manner that they can easily be divided into portions that contain either a maximum of 3 g (in case of one portion per day) or a maximum of 1 g (in the case of three portions) of added phytostanols/phytosterols. Meal replacement beverages and salad dressings shall be packed as single portions. The amount of phytostanols/phytosterols per container of beverages shall not exceed 3 g.

3.1.7. Nutritional Benefits to the population

A large body of scientific research dating back to the 1950s has documented the ability of phytosterols to reduce blood cholesterol levels without significant side-effects. Since then, the persuasive body of evidence supporting the cholesterol lowering effectiveness of sterols and sterol esters has been combined.

Epidemiological studies estimate that on average, a 1% reduction in cholesterol will reduce the risk of CHD by 2%. Furthermore, studies indicate that the greatest long-term benefit is obtained by early intervention. In 1998, the West of Scotland Coronary Prevention Society suggested that a 10-19% reduction in LDL-Cholesterol may reduce the risk of cardiovascular disease by as much as 41%. Studies have demonstrated that

consuming phytosterols can normally lower cholesterol within 30 days, following a recommended dosage in conjunction with a low fat diet and exercised.

The phytosterols and phytosterol esters that are the subject of this notification are comprised of the soyabean oil-derived sterols mentioned above in the specifications. The intended application of these phytosterols will be for use as an ingredient in various foods that have been notified and accepted by the EC.

The recommended intake on the labels of these novel foods will be 2-3 servings per day from the range of foods containing phytosterols. This will be equivalent to a daily intake of 2-3 g free phytosterols.

4. SAFETY ASSESSMENT

Sterols are GRAS evaluated by a panel of experts qualified by experience and training and determined to be safe under the specified conditions of use in the GRAS notification to the FDA.

Naturis sterols requires low daily dosage to provide efficacy - 800 mg per day - well within daily safety limits established or recommended by regulatory agencies in Europe and the United States.

Furthermore, the projected consumer exposure of Naturis sterols in functional food and nutraceutical applications is consistent with the ranges established with other substantially equivalent phytosterol containing products already approved and being sold in various countries around the world.

The pre-market assumptions from the post Launch Montering Report (SCF 2002) confirmed that the average daily free phytosterol intake would be 1.6-2.4 g/day.
As an official endorsement of safety, the US National Cholesterol Education Program (N.C.E.P) recommended consumption of 2 grams per day of phytosterols as part of the updated "clinical primary prevention" guidelines for coronary heart disease in May 2001. N.C.E.P also advises physicians on how to make their patients aware of phytosterol-enriched foodstuffs that may be combined with healthy lifestyle changes as a strategy to reduce high cholesterol.

Phytosterols are considered to be equivalent with regard to their potential toxicological effects, metabolic handling and biological activity. There are many published safety studies on plant phytosterols demonstrating their low order of toxicity. It is important to note that man does not synthesize these compounds and exposure is strictly from vegetable sources in the diet. Further, plant sterols are an essential component of the membranes of all eukaryotic organisms. Phytosterols do not produce adverse effects even

at high doses except in individuals with sitosterolemia, an inherited and very rare lipid disorder. It has been suggested that there may be consumer concern of over dosing by adding phytosterols to food products. This would theoretically occur either as a result of over-indulgence of food containing the phytosterols, or combining excessive quantities of food products that also contain phytosterols. However there is little cause for concern for overdosing as indicated by the long-term experience with Cytellin™ (Eli Lilly pharmaceutical preparation used to treat Hypercholesterolaemia from the 1950's to 1980's in the USA), a lipid lowering drug, where the recommended dose was 6 to 18 g per day.

4.1.1 RISK ASSESSMENT

Determination of the no-observed adverse effect level

The acceptable daily intake (ADI) is set on the basis of the highest no-observed adverse effect level (NOAEL) in animal studies (JECFA, 1987). The NOAEL for phytosterol esters was established by the 13-week rat feeding study. It is the study of longest duration with phytosterol esters and was conducted according to OECD guidelines that require intensive and extensive examination of the animals. In this study, rats received phytosterols (as phytosterol esters) in their diet at levels of 0, 0.1, 1, 2, or 5%. A dietary level of 5% is generally recognised as the maximum level required for the testing of non nutritive components, without having to modify the diet to maintain nutritional balance (FDA, 2002). There were no adverse effects at the highest concentration and therefore it can be used as the NOAEL. Mean daily intake of phytosterols over the 13 weeks was 3900mg/kg body weight/day in males and 4200mg/kg body weight/day in females. The mean value (4.1g/kg body weight/day) will be used in the risk assessment

Sterols are GRAS (Generally Recognized As Safe) which was evaluated by a panel of experts qualified by experience and training and determined to be safe under the specified conditions of use in the GRAS notification to the FDA.

Naturis sterols requires low daily dosage to provide efficacy - 800 mg per day - well

within daily safety limits established or recommended by regulatory agencies in Europe and the United States.

Furthermore, the projected consumer exposure of Naturis sterols in functional food and nutraceutical applications is consistent with the ranges established with other substantially equivalent phytosterol containing products already approved and being sold in various countries around the world.

The European Commission Directorate-General for Health and Consumer Protection has recently posted a listing of novel food notifications as of September 2005. Since July of 2004, as listed from Numbers 27-50, there have been approximately 19 notifications approved in the UK, Finland, and Ireland for phytosterols and phytosterol esters from vegetable and tall oil sources for multiple food types, generally under substantial equivalence to phytosterols authorized by Commission Decision 2004/845/EC. As listed in Numbers 42-43, the Finland food authorities have approved the addition of phytosterols and phytosterol esters for the same spectrum of consumer products that is being requested in this notification for the Forbes Medi-Tech products.

4.1.2 TOXICOLOGICAL INFORMATION

There is a history of safe consumption of phytosterols within the normal dietary intake of between 200-400mg/day. A comprehensive safety testing programme was carried out by other petitioners to address:

- mutagenicity,
  Absorption
  sub-chronic toxicity
  reproductive toxicity (including oestrogenicity), and olerability of high doses in humans.

The conclusions from these studies were as follows:

No evidence of genotoxicity[1]

No evidence of subchronic toxicity – NOAEL of 4.1g phytosterols/kg/bodyweight/day in a 90 day rat feeding study[2]

No effect on the reproductive system, and no oestrogenic activity[3,4]

A full toxicological assessment of phytosterol using the above studies and data available from the literature was carried out as part of the previous Novel Foods submission (Unilever documents D97/042, D98/002 and D98/028).
Based on this assessment, the EC Scientific Committee on Foods concluded that the use of phytosterol esters in yellow fat spreads at a maximum level, corresponding to 8% free phytosterols, is safe for human use.
Further SCF assessments on phytosterols and their esters from ADM (SCF 2003), Multibene (SCF 2003a), Oy Karl Fazer AB, Pouttu Ltd. and Teriaka Ltd. (SCF 2003b) also considered the other envisaged applications to be safe.
Since Cognis' phytosterols and their esters are identical in composition and manufacturing to those currently used, accordingly, the respective safety assessments are applicable.

An Acceptable Daily Intake (ADI) can be calculated from the NOAEL/safety factor method JECFA (1987). The generally accepted ADI for phytosterols based on animal studies at the highest doses tested is about 130 mg/kg/day. This may be a conservative estimate as there were no adverse toxicological findings at the highest dose level tested (equivalent to 5% phytosterols in the diet) and an effect level could not be determined due to the nutritional limitations of testing higher doses. This ADI is also consistent with the assessment of the US FDA in their acceptance of GRAS notifications on phytosterols. As noted in the Lipton GRAS document and ADM GRAS notification GRN 000061 (FDA, 2001), the ADI for phytosterols based on animal studies at the highest doses tested was 130 mg/kg/day. This equates to a daily intake of 9.1 g/day for a 70 kg adult.
With proper labelling, it is considered unlikely that consumption will exceed 3 g/day, even if the sterols and sterol esters are present in multiple and competing novel foods on

the market. In conclusion, dietary plant sterols and sterol esters are considered to be a safe and effective means for lowering blood cholesterol levels in consumers.

6. REFERENCES

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8. APPENDICIES

8.1.1 *Certificate of Analysis 1*

Certificate of Analysis

GF–95 Sterols

Non-GMO

GF-95 Sterols are crude phytosterols exclusively from GMO-free Soybeans.

Analysis Date : 4/18/06

Sample Lot #: 041806

Sterol Components

Brassicasterol	0.00%
Campesterol	27.79%
Campestanol	1.40%
Stigmasterol	3.55%
b-Sitosterol	55.70%
b-Sitostanol	3.69%
Total Major Sterols	**92.13%**
Other Sterols	2.94%
Total Sterols	**95.07%**
Total Steradienes	**0.00%**

Properties

Acid Value	2.0 max	passed
Ash Content	0.1% max	passed
Melting Point	143-149°C min	passed
Appearance	Free flowing pastilles	passed
Color	White	passed

8.1.2 ***Certificate of Analysis 2***

Product Data Sheet

GF-95 Sterols

GF-95 Sterols are crude phytosterols derived exclusively from GMO-free soybeans.

GF-95 Sterols are certified kosher.

Properties

Major Sterols (includes b-sitoterol, b-sitostanol, campesterol, stigmasterol, campestanol, and brassicasterol)	95% min
Acid value	2.0 max
Ash content	0.1% max
Melting Point	143-149°C min
Appearance pastilles	Free flowing
Color	White

8.1.3 ***Certificate of Analysis 3***

Certificate of Analysis

PRODUCT NAME: GF-95 Sterols

ANALYSIS DATE: November 13, 2006

LOT NUMBER: 111306

STEROL COMPONENTS

Brassicasterol 0.00 %
Campesterol 27.29 %

Campestanol	1.36 %
Stigmasterol	3.45 %
b-Sitosterol	55.20 %
b-Sitostanol	3.69 %
Major Sterols	**90.98 %**
Other Sterols	2.94 %
Total Sterols	**93.92 %**
Total Steradienes	**0.00 %**

8.1.4 Certificate of Analysis 4

Certificate of Analysis

PRODUCT NAME: GF-95 Sterols

ANALYSIS DATE: May 16, 2007

LOT NUMBER: 051607

STEROL COMPONENTS

Brassicasterol	0.00 %
Campesterol	27.34 %
Campestanol	1.28 %
Stigmasterol	3.50 %
b-Sitosterol	55.29 %
b-Sitostanol	3.70 %
Major Sterols	**91.11 %**
Other Sterols	3.03 %
Total Sterols	**94.14 %**
Total Steradienes	**0.00 %**

8.1.5 Certificate of Analysis 5

Certificate of Analysis

PRODUCT NAME: GF-95 Sterols

ANALYSIS DATE: February 20, 2007

LOT NUMBER: 022007

STEROL COMPONENTS

Brassicasterol	0.00 %
Campesterol	27.33 %
Campestanol	1.40 %
Stigmasterol	3.39 %
b-Sitosterol	55.17 %
b-Sitostanol	3.72 %
Major Sterols	**91.01 %**
Other Sterols	2.96 %
Total Sterols	**93.97 %**
Total Steradienes	**0.00 %**

8.1.6. Product Specification

Non-GMO, Oilseed Phytosterols
Specification

Description: A Crystalline material derived from oilseed distillate.

Applications:
1) In nutraceutical applications to reduce serum cholesterol
2) In cosmetic applications as an emulsifier, emollient and skin softener in lipstick, skin a hair care products
3) As a fermentation substrate for pharmaceuticals

Specifications

Appearance	White Crystalline
Color	1 Gardner Maximum
Loss on Drying	Less than 1%
Residue on Ignition	0.5% Maximum

Soluble in Mineral Oil, Squalane, Isopropyl Palmitate and Vegetable Oils
Insoluble in Water, Ethanol and Propylene Glycol

Particle Size

Prills	98% passes USS#30 Screen
Powder	95% Passes USS#100 Screen

Chemical	Limits	Typical
Total Sterols	94% Minimum	96.0%
Brassicasterol	3% Maximum	1.4%
Beta Sitosterol	50% Minimum	52.0%
Campesterol	20% Minimum	35.0%
Stigmasterol		3.0%

The bulk of the remainder is: Minor sterols such as ergosterol, avenesterol, 24 methyl die isomers, 24 ethyl di and tri ene isomers and long chain aliphatic alcohols (<0.5%)

Heavy Metal

As Pb	1ppm Maximum

GMO Status
All vegetable can be certified as non-GMO

Naturis 94% Sterol Composition as free sterols	**Typical Concentration as Free Sterols (wt %)**	**Typical Concentration as Free Sterols (relative wt %)**
B-Sitosterol	52%	55%
Campesterol	35%	37%
Stigmasterol	3%	3%
Brassicasterol	1.4%	2%
Other Sterols	<3%	3%
Total Sterols	94%	100%
Sitosterol + Campesterol + Stigmasterol, as a percent of Total Sterols*	90%	95%