FOOD STANDARDS AGENCY

Mr M. Jaume Torres
Prima Pharm BV
2514BP Hague
Netherlands

20th December 2005 Reference: NFU 583

[By e-mail]

Dear Mr Torres,

REQUEST FOR AN OPINION ON THE SUBSTANTIAL EQUIVALENCE OF PHYTOSTEROLS FROM PRIMA PHARM

The Advisory Committee on Novel Foods and Processes (ACNFP) has now finalised its assessment of your request for an opinion on the substantial equivalence of phytosterols from Prima Pharm as a food ingredient compared with the existing phytosterols marketed by Teriaka. The phytosterols are to be used in yellow fat spreads, milk based fruit drinks, yoghurt type products, cheese type products, milk type products, soya drinks and fermented milk products.

I am pleased to inform you that, in view of the positive opinion given by the ACNFP, the Food Standards Agency, the UK Competent Authority for all novel food issues is content that your phytosterol ingredient meets the criteria for equivalence, as defined in Article 3(4) of Regulation (EC) 258/97.

You should ensure that all products containing phytosterols are marketed and labelled in

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accordance with European Community Law and any relevant national provisions, in particular with regards to (EC) 608/2004.

Please note that, in accordance with Article 5 of (EC) 258/97, you should notify the European Commission of your intention to market your phytosterols when they are first marketed. This notification should be sent (with the UK opinion) to Mr Andreas Klepsch at the following address:

European Commission
DG SANCO
Rue de la Loi 200
B-1049
Brussels
Belgium

If you have any other queries please do not hesitate to contact me.

Yours sincerely

Dr Chris Jones
Novel Foods, Additives and Supplements Division

Enc: ACNFP's Opinion

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON SUBSTANTIAL EQUIVALENCE OF PHYTOSTEROLS CONSIDERED UNDER ARTICLE 5 OF THE NOVEL FOODS REGULATION

Applicant **Prima Pharm BV**
15, Nieuwe Uitleg
2514BP Hague
Netherlands

Responsible Person **Mr M. Jaume Torres**

Introduction

1. A request was submitted by Prima Pharm to the UK competent authority for an opinion on the equivalence of their phytosterols to the phytosterols marketed by Teriaka which were authorised by Commission Decision 2004/336/EC. In July 2004 and October 2004 Teriaka obtained opinions on equivalence from the Finnish competent authority that extended the range of foods that their phytosterol ingredient could be incorporated into. These are, yellow fat spreads, milk based fruit drinks, yoghurt type products, cheese type products, milk type products, soya drinks, and fermented milk products. Teriaka notified the Commission of the placing on the market of their products in accordance with Article 5 of regulation (EC) 258/97 on 16 July 2004 and 16 November 2004. Prima Pharm are therefore entitled to seek a view on equivalence for the use of their phytosterol ingredient in each of the food categories included in Teriaka's original authorisation and the two subsequent notifications granted by the Finnish competent authority.

2. According to Article 3(4) of (EC) 258/97, the notification procedure applies to, "foods or food ingredients… which on the basis of scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies…. are substantially equivalent to existing foods or food ingredients as regards their:

   - Composition
   - Nutritional value
   - Metabolism
   - Intended use
   - Level of undesirable substances contained therein."

Composition

3. The Applicant is claiming equivalence to the specification of phytosterols set out in Annex 2 of Commission Decision 2004/336/EC. Prima Pharm obtain their phytosterols from the company les Derives Resiniques et Terpeniques (DRT). It should be noted that the data on DRT's tall oil phytosterols were included in Teriaka's original novel food application, along with data from another supplier of phytosterols derived from vegetable oils. However, although DRT's phytosterols have been through the authorisation process they have not been used by Teriaka since gaining approval.

4. The product produced by the applicant is made from tall oil pitch from *Pinus maritima* (synonym *Pinus pinaster*) a species of pine tree. It is manufactured in the same way as the approved phytosterol product and involves extraction, crystallisation and drying. The specification of the product described by the applicant is consistent with that described in Commission Decision 2004/336/EC.

5. To comply with the conditions set out in Commission Decision 2004/336/EC for phytosterols and phytostanols extracted from sources other than vegetable oil, all batches of the product will have a purity of more than than 99%.

Discussion: *The Committee noted that data provided on the composition of Prima Pharm's phytosterols complied with the specification of phytosterols in Commission Decision 2004/336/EC.*

Nutritional value and metabolism

6. The nutritional value and metabolism of Prima Pharm phytosterols are expected to be the same as those marketed by Teriaka. Anticipated intake of phytosterols is not likely to be increased as the ingredient is to be used in the same range of products already approved.

Intended use

7. The applicant intends the ingredient to be used in yellow fat spreads, milk based fruit drinks, yoghurt type products, cheese type products, milk type products, soya drinks, and fermented milk products. These products are the same as existing products on the market containing Teriaka phytosterols that were authorised in Commission Decision 2004/336/EC and the two subsequent notifications issued by the Finnish competent authority in July and October 2004.

Discussion: *The Committee is content that the applicant's product is to be consumed at the same level and in the same range of products as the existing product.*

Level of undesirable substances

8. The applicant gave detailed information on the levels of a number of classes of potential contaminants including dioxins, polycyclic hydrocarbons, herbicides, pesticides and heavy metals. All contaminants measured are within acceptable levels in compliance with EU regulations.

Further Information

9. In accordance with the guidelines on substantial equivalence the applicant also submitted data from some studies carried out with DRT's phytosterols. These studies addressed acute toxicity, skin irritation and skin sensitisation. These studies were evaluated as part of the earlier application from Teriaka. No adverse results were reported in any of these studies.

Conclusion

10. The Committee is content that the applicant's approach to demonstrating the equivalence of their phytosterols with the existing phytosterol ingredient is consistent with the criteria set out in Article 3(4) of the Novel Food Regulation (EC) 258/97.

11. Therefore phytosterols marketed by Prima Pharm can be considered to be substantially equivalent to the existing phytosterol ingredient marketed by Teriaka.

12. Prima Pharm should ensure that the labelling of products containing their phytosterols comply with Commission Regulation (EC) 608/2004 concerning the labelling of foods with added phytosterols, and more specifically to Article 2 of this regulation.

December 2005