

Mr. David Tiffney/Mr. Bob Andrews

Hygieia Global Health Products
C/- Bldg # 54, 5/F
No. 1089 N. Qinzhou Rd
Shanghai 200233
CHINA

March 26, 2008

Dear Mr. Tiffney,

I am contacting you in regard to your application for an opinion on the substantial equivalence of GlucosaGreen[®] branded glucosamine HCL under *Article 5* of the novel food Regulation EC No. 258/97. You propose to use GlucosaGreen[®] branded Glucosamine HCL in food supplements on the EU market based on its substantial equivalence to a shellfish counterpart in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances.

Based on the information provided by you, the FSAI concludes that GlucosaGreen[®] branded glucosamine HCL is substantially equivalent to glucosamine HCL from shellfish that is already on the EU market in supplement form. This opinion is subject to agreed labelling of products containing the fungal ingredient which will be produced to the specifications outlined in the application and used only in food supplements, in accordance with Directive 2002/46/EC. A summary of the information considered and the FSAI opinion is included.

If you are satisfied with this opinion, you should notify the European Commission, in accordance with *Article 5* of Regulation EC No. 258/97, before you place this product on the market. In order to avoid any confusion, I recommend that you await a response from the Commission prior to placing the product on the market.

Commission contact details:

Mr Andreas Klepsch
European Commission
DG SANCO
Rue de la Loi 200
B-1049, Brussels
Belgium

Regards,

Dr. Pat O'Mahony
Chief Specialist, Biotechnology

SUBSTANTIAL EQUIVALENCE OPINION

GlucosaGreen[®] branded Glucosamine HCL

On January 9th 2008, the FSAI received an application from Hygieia Global Health Products for an opinion on the substantial equivalence of glucosamine HCL from *A. niger* (GlucosaGreen[®]) to its existing shellfish counterpart. The initial application, along with subsequent information and clarifications provided by the applicant were reviewed by the FSAI to determine the substantial equivalence of these products with respect to composition, nutritional value, metabolism, intended use and level of undesirable substances.

In August 2004, the UK Food Standards Agency provided an opinion to Cargill Acidulants to the effect that Glucosamine HCL from *A. niger* for use in food supplements and PARNUTS products was substantially equivalent to that derived from shellfish for the same uses.

Composition

Glucosamine is a naturally occurring amino sugar, derived from glucose, which forms an essential intermediate in the energy metabolism of multi-cellular organisms. Glucosamine has been derived from fish by-products (e.g. crustacean shell) since the mid-20th century, but reports of its potential therapeutic value have resulted in increased demand.

The structure of glucosamine HCL from *A. niger* and shellfish was shown by the applicant to be identical through infrared absorption, ¹H NMR, ¹³C NMR and mass spectrum. The production process for shellfish and fungal glucosamine HCL products are the same except for the starting material, resulting in a white crystalline powder of greater than 98% purity. The starting material for the GlucosaGreen[®] product is *Aspergillus niger* biomass, a by-product of citric acid production. The results of tests on three batches of glucosamine HCL from both sources reveal almost identical content for a variety of parameters.

Nutritional Value and Metabolism

Glucosamine HCL is a single molecule and its nutritional value and metabolism does not vary with the source of the raw material. The applicant provides a table of nutritional data that shows the levels of fat, protein, carbohydrate, calories etc. are identical for glucosamine HCL from both sources.

Intended Use

The applicant intends to use GlucosaGreen[®] in food supplements, similar to that for the shellfish-derived counterpart. The applicant notes that there is no established formal RDI for glucosamine HCL and that the most widely accepted intake level is up to 1,500mg per day. The applicant will provide the fungal glucosamine HCL in supplement form at dosages similar to its existing shellfish counterpart.

Levels of Undesirable Substances

A. niger is not known to be toxic or pathogenic for humans. The source of raw material for the production of GlucosaGreen[®] is *A. niger* biomass, a by-product of the citric acid production process. The release specifications for glucosamine HCL produced from shellfish and *Aspergillus niger* sources are similar, with additional tests for Ochratoxin A conducted on the fungal sourced material as some strains of *A. niger* may produce that toxin. The tests for microbial contaminants yield identical results for product derived from both sources.

Labelling

The applicant provided a copy of the proposed label which includes the words “Derived from *A. niger*” prominently displayed, among other details.