

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labelling and Dietary Supplements  
5100 Paint Branch Parkway  
College Park, Maryland 20740  
USA

Att: Felicia Billingslea

Copenhagen 4<sup>th</sup> of December, 2006

Submission of Notification under 21 U.S.C. § 343(w)(7) for Exemptions from Food Allergen Labeling.

We hereby submit our documentation on the main ingredient Biomarine Complex in Imedeem Oral Beauty products in order to obtain exemption from the Food Allergen Labeling.

For some weeks we have tried to get in touch with FDA in order to be informed about the requirements for information for such a Notification. We understand from your emails to Cassandra Soltis that there are no guidelines for the type of data needed to support the notification.

Imedeem products have been produced and sold by Ferrosan A/S since 1993. Today the products are sold in 52 countries worldwide, including USA, where we have been granted an exemption for the current batches.

The Imedeem Classic<sup>TM</sup> was the first oral skin product on the market. Ferrosan A/S have been the main marketer of Oral Skin Care products ever since.

Ferrosan's US Corporation, Ferrosan Inc., sells two skin rejuvenating tablets in the US - Imedeem Time Perfection<sup>TM</sup> targeted to women 35 to 50 years of age and Imedeem Prime Renewal<sup>TM</sup> targeted to women postmenopause (50+ years of age). These tablets are sold by doctors, spas, apothecaries, beauty e-tailers and Imedeem.us, Ferrosan Inc.'s website.

Main ingredient in the Imedeem products is Biomarine Complex - an extract of Deep Sea Fish.

Extraction includes hydrolysis by protease. Result is a purified extract containing peptides of 8- 23 amino acids.

Imedeem products and ingredients are safe. We continuously survey the safety and efficacy (in vivo and in vitro) of the products. Number of reported events from 1993 to 2005 is stable of approx. 25 per year. These are mostly skin related (red spots and other minor reactions). Only a few serious adverse events have been reported and none of these have been classified as having probable causality to Imedeem and subjects recovered completely.

To obtain the above mentioned Exemption we have conducted a study to demonstrate the lack of allergenicity of our product. A large study on the general population is not

sufficiently strong to our opinion. We have therefore conducted a focussed study on a selected population with diagnosed food allergy, and we have also investigated if our ingredient contains the most dominant fish allergen Gad c 1.

We included frozen fish meat and bone in the test.

The study clearly demonstrates that people with known food allergy react to cod meat, but show no reaction to lmedeen.

This is to us very strong solid scientific state-of-the-art evidence for obtaining the exemption mentioned above.

If any questions please don't hesitate to call me.

Enclosed: 4 copies of study report + appendices.

Lotte Damgaard Valencia  
Project Manager.

Contact details:

Lotte Damgaard Valencia  
Ferrosan A/S  
Sydmarken 5  
2860 Soeborg  
Denmark

Telephone: +45 3958 5580  
Mobil: +45 2214 0489