



# proDERM Quick Facts on clinical studies with nutritional supplements

## Scientific evidence for products with health claims

### Introduction – Product claims must be evidence-based

The Regulation on “Nutrition and Health Claims Made on Food“ which was adopted in 2006 for the reason of consumer protection, heralded a paradigm shift in the handling of food claims. In addition to the positively assessed claims from the Community Register, the following now applies: The use of a claim is prohibited unless it has been explicitly examined and approved by the European Commission.

The EFSA (European Food Safety Authority) is responsible for examining claims. It ensures that each claim on a label marking a food in the European Union is non-ambiguous and **backed by scientific evidence**.

### Definition and Approval Process of Claims

"A 'claim' means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation in any form, which states, suggests or implies that a food has particular characteristics."

The Regulation provides for various approval procedures depending on the claim category:

	Claim-Category	Approval Procedure	Claim Examples
Art. 13	General Function Health Claims	The EFSA is currently evaluating the 4,637 claims collected in the Community Register and plans to finish this evaluation by 30 June 2011.	Nutrition-related: „energy-reduced“ Health-related: „improves skin condition“
Art. 13., Par. 5	New Function Health Claims	Separate approval and submission of a scientific dossier to the EFSA is required. Authorization procedure under Articles 15 - 18 of the Regulation.	
Art. 14	- Claims on Disease Risk Reduction - Claims on Child Development and Health	The European Commission and Member States decide on the basis of an EFSA opinion on the scientific substantiation of a claim as to whether it requires approval prior to use. If authorization is necessary, Articles 15 - 18 of the Regulation apply.	„helps with psoriasis“ „good for the growth of children“

## The scientific evidence of Health Claims -

### a matter for experts

Applications for new claims are frequently rejected by the EFSA. The basis of a successful application is the careful planning of the clinical trial. Especially for studies with food or nutritional supplements that promise particular characteristics related to skin or hair, very specific characteristics must be taken into account when preparing a study.



Thus, it is important to note, for example, that the substance has a long way to go from absorption and metabolism to the site of action. Therefore, demonstration of the desired effect requires an accurate sample size estimation and proper selection of suitable measurement methods. In addition, study participants should also be randomized into different treatment groups, with the inclusion of placebo groups. It might be necessary, that a high number of subjects must be included and the study be conducted over a long investigation period. In short: **The complexity of scientific evidence for health claims is high!**

### proDERM's service in the context of health claim studies

Since 1994, proDERM has conducted studies proving the efficacy of drugs, medical devices, cosmetics and nutritional supplements. Professionalism and science are our basic principles, and our studies are conducted according to ICH-GCP guidelines. The implementation of the EU regulation raises the standards for the scientific evidence of food health claims to a level that we have already been offering our customers for many years. As a proDERM customer, you will benefit from standardized processes in a new regulatory environment and from experience based on more than 100,000 studied subjects.



Our services include:

- **Study design consulting (design, collective, duration, inclusion and exclusion criteria) in order to obtain the highest evidence base**
- **Submission to the Ethics Committee**
- **Recruitment of volunteers**
- **Conducting of the study**
- **Data management and statistics**
- **High-quality study report**

From the claim concept to the statistical analysis with valid results, it must be remembered that an application for the approval of a claim will only be positively assessed if sufficient scientific evidence can be presented. **Choosing the right cooperation partner is therefore crucial to success.**

## Good to know

Measured against the effects of topical applications such as creams, the cosmetic effects provided by nutritional supplements are comparatively small. For this reason, the technology used to detect the effects has a particular significance.

Our **list of instruments** provides information on the essential procedures that we use. We want to especially emphasize the non-invasive skin test methods of Raman spectroscopy and confocal microscopy, as well as our USR-CliP (Unit for Standardized and Reproducible Clinical Photography), a state-of-the-art solution for high resolution clinical photography.

Other valuable information is provided by the EFSA website ([www.efsa.europa.eu](http://www.efsa.europa.eu)) and its „Register of Questions“ portal (<http://registerofquestions.efsa.europa.eu>), where current health claims applications and their processing status are listed.

We are also pleased to be available to you personally. In this case, please contact

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