

In the nutraceuticals world, claims based on proof of safety and efficacy are important, principal keys to success. Market growth or market decline are very much dependent on the solidity and acceptability of claims. And false, unjustified claims can ruin a market segment very quickly.

The recent history of the herbal market in the U.S. demonstrates two extremes: quick growth of the market and then decline, all within a very short period of less than 10 years. Solid science, mostly

Safety is the other very important issue. Safety is the easiest way for authorities to attack a particular natural product, whether it is scientifically justified or not. Safety discussions regarding kava are what led to the ban on all kava products in Europe. Even though the evidence was very poor, authorities argued that the efficacy was not well proven. Therefore, only minor doubts about the safety could be used to justify a ban. If there had been better clinical trials on the efficacy, in addition to more toxicological data about the safety, the worldwide kava debacle could probably have been avoided.

The claims regulations, especially for supplements and food products, are under international scrutiny to better define how health claims and nutritional claims should be substantiated. In Europe, a new proposal for the use of nutrition and health claims on food is presently being discussed. What we can expect to see is better-defined regulations and approval procedures, which will affect almost every claim made for food products. Charitable endorsements or professional recommendations will more than likely be prohibited. The scientific substantiation of claims will be very well described and defined and will require an approval process for all health claims. In addition, a list of "well-established" claims will be developed. Data protection and commercial confidentiality of scientific dossiers for those companies who invest in clinical trials to document and substantiate the claims for their products is very important, so that other companies cannot automatically "borrow" the claims. This incentive is crucial to initiate new research. While many European producers of natural products, especially of herbal products, have invested in clinical research, many U.S. producers have in the past borrowed the science, even when the products were not comparable, had different dosages, composition, etc.

The situation in the U.S. is changing, however, as more research is being undertaken. These efforts are essential to secure the market, initiate new PR information, substantiate claims for products and document both the efficacy and safety in a scientific manner. *NW*

Rebuilding The Market

More clinical trials are needed to stimulate growth.

By Joerg Gruenwald

coming from Europe, stimulated market growth in the second half of the 1990's, where the key botanicals ginkgo, St. John's Wort, saw palmetto and garlic skyrocketed in sales and created a totally new awareness of natural products, which were seldom used by the mainstream consumers previously. This trend hit a wall for several reasons, mostly due to negative press, information about false labeling and misleading claims made for products, combined with a few negative or incorrectly interpreted clinical trials. As a result of these factors, an unjustified negative image of these products was created. Consequently, consumers then began to question all labels and claims. Self-regulation by the industry to control false claims did not function effectively and the market began its decline.

So how can the industry regain a positive reputation and rebuild a strong market specifically for herbal products? One important factor is quality control; the first steps have been taken with the new guidelines for Good Manufacturing Practices (GMPs) for supplements. In addition, there is a need for solid new clinical trials, which can positively influence consumers, so that they will again begin to rely on those natural products, which are based on solid science and proven to be safe and effective.

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