Moving Japanese Enzymes to the US Dietary Supplement Market
– Importance of New Clinical Research and Scientific Data –

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1. What is a Dietary Supplement?

The term "dietary supplement" is defined in the US Dietary Supplement Health and Education Act (DSHEA) of 1994 [(1)]. A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, soft gels or etc. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of "foods", not drugs, and requires that every supplement be labeled a dietary supplement.

The dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. The FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market.

2. Introducing Enzymes into the US Dietary Supplement Market

In Japan, enzymes sold to consumers for healthcare are strictly drugs. In contrast, enzymes for healthcare can be marketed as dietary supplements in US. Some enzymes (lactase, α-galactosidase, etc.) have already penetrated the US consumer market and play an important role in promoting healthy living. However, there are potentially other enzymes which could contribute to US healthy living as dietary supplements

3. US-Dietary Supplement Claim Categories

There are three categories of claims associated with the labeling of dietary supplements [(2)]:

1) Nutrient content claims
2) Structure/functional claims
3) Health claims

Health claims characterize the relationship of a substance to a disease or health-related condition. Health claims require strong scientific evidence and very likely clinical studies, and must be approved by the FDA prior to sales.

Here, I would like to present some of our on-going projects which will, we hope, bring some of our traditional enzymes to the US-Dietary Supplement industry with novel efficacies.

4. Seaprose S® as an PAI-1 Inhibitor

Cardiovascular disease (CVD) is the No. 1 killer of men and women in the world. CVD is responsible for 40% of all deaths in the US with a cost estimated at $431.8 billion in 2007.

Plasminogen activator inhibitor type 1 (PAI-1) is the major negative regulator of tissue-type plasminogen activator (tPA) in the fibrinolytic system [3]. High levels of PAI-1 reduce fibrinolytic potential and can therefore contribute to the development of thrombosis. Thrombotic cardiovascular diseases are particularly evident in elderly populations, but they are also induced in a variety of pathologies such as obesity, diabetes, chronic inflammation, chronic stress or metabolic syndrome which are conditions that result in high levels PAI-1[4, 5].

A number of PAI-1 inhibitors have been reported recently. These include small molecules, antibodies, and peptides [6-9], but they will take years to become commercially available. Thus, there is a need for enzymes that can safely inhibit PAI-1. We have done extensive *in vitro* tests to prove Seaprose S® should inhibit PAI-1 safely in humans. We further proved the novel efficacy with one small clinical study, and a 2nd clinical study is under way.

5. Digestive Enzymes to Ease Dyspepsia

In the US, digestive health has never been a popular topic of conversation. However, it has been slowly moving toward the forefront of the public health forum, and millions of people have decided to break their silence about constipation, bloating and gas. In an aging population and stressful society, the digestive health market will be very active for years to come.

A clinical study in China, using a visual analog scale, showed that digestive enzymes decreased the symptoms of early satiety, stomach discomfort and abdominal distension. In order for digestive enzymes to be more widely accepted in the US population, it is essential to have clinical data which is well received from professionals and consumers. We are currently testing a new technology to show how digestive enzymes affect the digestive system by using the "SmartPill" GI Monitoring System [10].

References

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