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Approval of Dietary Health Supplement in Korea

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Functional food is regulated by Dietary Health Supplemnt Act (DHSA) in Korea. But functional food regulated by DHSA is not conventional functional food but supplement for health promotion. DHSA defines Dietary Health Supplement as "A product that is intended to use enhance and preserve the human health by the functional food ingredients in forms of tablet, capsule, powder, granule, pill or liquid". DHSA authorizes Korea Food & Drug Administration to regulate dietary health supplement (DHS). DHS are categorized into two classes according to differences in regulation system: generic DHS and product-specific DHS. Generic DHS is regulated by standard without pre-market approval, but product-specific DHS is requiring pre-market approval. Generic DHS contain 32 products including nutrient supplements. And these 32 products have already been regulated Food Sanitation Act before January, 2004. Generic DHS may be manufactured by only notification to KFDA without any approval or permission, provided that they meet the established standards and specifications of Dietary Health Supplement Code. Generic DHS is not individually approved because it is regulated by standard. Pre-market approval for product-specific DHS requires scientific evidences that an active food ingredient is safe and effective before marketing. Also pre-market approval for product-specific DHS requires establishing standards and specifications of a product containing approved active food ingredient before marketing. Every product-specific DHS must be approved individually by the KFDA after rigorous evaluation of the safety and effectiveness of proposed health benefit claims on scientific evidience base. This means that carefully planned human clinical trials, along with *in vitro* and *in vivo* animal studies. The efficacy of product-specific DHS is evaluated by three steps. First, review individual studies in terms of study type and quality. Second, review totality of evidence in terms of amount, consistency and relevance. Third, report the rank and appropriate qualifying language according to the level of evidences.