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Psychobiotic PS128 registration, health claims approved in Thailand, Canada

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Psychobiotics are probiotics that can yield specific benefits to the nervous system



Bened Biomedical has announced recent approval of the company's probiotic *L. plantarum* PS128 in Thailand and Canada. Authorities in each country also endorsed health claims that may be made about the strain. Local distributors will launch PS128 products this year.

Regulations on probiotics differ from country to country, so strains often undergo a unique registration process in each new market before sale approval. Some are more elaborate, requiring detailed stability data and safety tests using specialized techniques. Others are less rigorous, with relatively simple methods. In some locations, health claims are part of the registration procedure, but in others, they are part of a separate application.

When Interpharma, a biopharmaceutical company headquartered in Thailand, expressed interested in adding PS128 to a new product, the probiotic was not on the Thai FDA's list of approved species. It needed to acquire special approval before being imported and sold in Thailand.

Bened's team in Taiwan worked closely with Interpharma during the process. The first step was a safety assessment application, and detailed technical safety reports were prepared for regulators. Bened also provided clinical studies and other information about PS128's effectiveness, and Thai health regulators ultimately permitted specific claims to be made about the strain. These include PS128's potential neurological and mental health benefits, such as improving sleep and reducing symptoms like those seen in anxiety, depression, autism, and Parkinson's disease.

In Canada, PS128's Class 1 application has already been accepted by Health Canada, the federal health department. The strain may be sold in the country with claims of general probiotic gut health. Bened is currently working on a Class 3 application, which would allow for additional PS128 health benefit claims to be made.