



NATURAL AND NON-PRESCRIPTION HEALTH PRODUCTS DIRECTORATE

Company Code: 63180
File Number: 667005
Submission Number: 667005

Mr. Donghoon Oh
Ildong Bioscience Co., Ltd.

Dear Mr. Donghoon Oh:

**Re: Product Licence Issuance - NPN 80119568
General (non-traditional) - *Lactiplantibacillus plantarum* IDCC 3501 (Powder)**

The Natural and Non-prescription Health Products Directorate (NNHPD) has reviewed your submission and concluded that, based on the information included as part of your submission, it complies with the Product Licence Application (PLA) requirements of the *Natural Health Products Regulations* (NHPR). Please find enclosed a copy of the Product Licence (PL), which is issued pursuant to s. 7 of the NHPR and authorizes the sale of the product described therein.

If you notice any discrepancies concerning the information on the PL in comparison to the last submitted PLA form, please submit a notice entitled "Request for Correction to the Product Licence" indicating the corrections to be made, within 60 days after the day on which the product licence is issued, to NNHPD_DPSNSO@hc-sc.gc.ca. The File Number (provided at the top right corner of the title page) and Product Number must be quoted on all future correspondence regarding this product.

Keeping Product Licence(s) Up-To-Date

Any changes made in respect of a PL may require the submission of an amendment and/or notification and must be submitted using the [Amendment and Notification Form \(ANF\)](#) pursuant to sections 11, 12 and 13 of the NHPR.

Regulatory Responsibilities

PL holders are responsible for complying with the [Food and Drugs Act](#) and the [Natural Health Products Regulations](#), including,

- Providing NNHPD with the site information outlined in section 22 of the NHPR prior to commencing the sale of the natural health product pursuant to section 12(2)(b) of the NHPR. The NNHPD also requests that you provide any updates to this information through a notification;
- Only selling natural health products that are manufactured, packaged, labelled, imported, distributed or stored in accordance with Part 3 (Good Manufacturing Practices) of the NHPR (or in accordance with equivalent requirements if the natural health product is

imported).

With respect to the finished product specifications/Finished Product Specifications (FPS) form you have submitted, we acknowledge receiving the quality information provided and have placed the FPS on file. However, we are informing you through this notice that the quality information has not been reviewed for accuracy, and, therefore, the FPS shall not be considered approved. You are reminded that product licence holders are ultimately responsible for ensuring the quality of their licensed NHPs, including the establishment of the finished product specifications, as per section 44 in Part 3 of the NHPR, that ensure a products compliance with the NHPR.

- Complying with the advertising and labelling requirements under section 9 of the FDA and Part 5 of the NHPR, including presenting label information in both French and English (section 87 of the NHPR).

NNHPD has not verified the veracity of the marketing terms on NHPs. Additional information on acceptable advertising claims can be obtained from the [Consumer Advertising Guidelines for Marketed Health Products \(for Non-prescription Drugs including Natural Health Products\)](#). Licensees should possess evidence of certification or proof that the marketing statements (terms) are truthful and accurate and meet the necessary certifications. The certification or proof should be available to HC upon request.

A contravention of the [Food and Drugs Act](#) and the [Natural Health Products Regulations](#) provisions, including those highlighted above, may result in the suspension and cancellation of product licence(s) (sections 18-21 of the NHPR) and/or other compliance and enforcement action.

Yours truly,

Submission Management Division
Bureau of Product Review and Assessment
Natural and Non-prescription Health Products Directorate

encl.: Product Licence
c.c.: Tania John