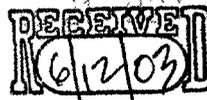


1824 South Robertson Blvd.
Los Angeles, CA 90035-4317
310/204-6936 • 800/726-0886
www.Jarrow.com

FAX NUMBERS
Orders 800/890-8955
General 310/204-2520
Administrative 310/204-5132



May 28, 2003

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, Maryland 20740
Reference phone #301-436-2373

Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name of Address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

(2) Text of the statement(s):

TH-1 Probiotics™ contains tyndallized (heat killed) probiotic bacteria *Lactobacillus casei* and *Lactobacillus plantarum*, Organic Fermented Soy Milk and live *Bifidobacterium longum* BB536 (Morinaga strain). The metabolites of tyndallized *Lactobacillus casei* and *Lactobacillus plantarum* bacteria have been shown to support the production of certain cytokines (cell messengers) related to the TH-1 immune response, such as gamma interferon and interleukin 12 (IL-12).

Organic Soy Milk (GMO-free), fermented by *Lactobacillus casei* and *Lactobacillus plantarum* contains substantial amounts of beneficial metabolites of these immune-supporting bacteria. These metabolites include lactic acid, peptidoglycans, plantaricin and other bacteriocin compounds. After fermentation of the organic soy milk, additional tyndallized (heat killed) *L. plantarum* and *L. casei* are added.

L. plantarum is one of the major *Lactobacillus* species found in the human gut (mean counts are between 10^7 to 10^9 per gram). Tyndallized *L. plantarum* enhances the production of gamma interferon and interleukin-12 (IL-12).

L. casei has been shown to activate NK cell activity. The immunomodulating activity of tyndallized *L. casei* has been documented in experimental studies. *L. casei* is naturally found in the mouth and digestive tract, and is a lactic acid bacteria utilized worldwide for fermentation of milks.

Bifidobacterium longum BB536 was originally isolated from a healthy infant and its effects have been extensively studied for thirty years documenting its numerous benefits in maintaining healthy flora in the lower intestine. BB536 reduces putrefactive bacteria in the intestines by producing lactic acid, acetic acid and bacteriocins. Also, BB536 competitively decreases pathogenic bacteria such as *Bacteroides*, *Clostridium*, *Candida*, *Pseudomonas* and *Streptococci*. BB536 is also an important stimulant of the immune system, by its effects on immunoglobulin A (IgA). Furthermore, BB536 is supportive of detoxification processes in the body by its effects on lowering enzymes such as urease and deaminase.

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84713

(3) Name of the dietary ingredient(s) if not provided in the text of the statement:

Organic Fermented Soy Milk (fermented with L. plantarum R202 and L. casei R256) • Tyndallized (Heat Killed) Bacteria Lactobacillus casei R256
Lactobacillus plantarum R206 • Bifidobacterium longum BB536
(Morinaga Strain)(2 billion)

(4) Name of the dietary supplement(s)

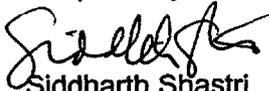
TH1 Probiotics™ 300 gm 10.5 oz powder

(5) The following disclaimer appears on the label in bold:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients.

Respectfully submitted,



Siddharth Shastri

Vice President, Product Development