

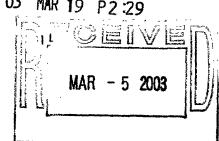
TAISHO PHARMACEUTICAL CALIFORNIA, INC.

1324 '03 MAR 19 P2:29

February 28, 2003

Via Federal Express

Office of Nutritional Products, Labeling and Dietary Supplements (HSS-800) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835



SECTION 403(r)(6) NOTIFICATION

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, Taisho Pharmaceutical CA, Inc. notifies FDA that it has been using the following sets of statements on the label of the Lipovitan® Healthy Heart Formula product. Each statement is based on the presence of the nutrients identified in the statement or discussed in other statements on this label. The statements all appear on the same panel as the statutory statement, "[t]he statements on this panel have not been evaluated by the FDA. This product is not intended to treat, diagnose or cure any disease."

Lipovitan® Healthy Heart Formula

- Lipovitan is a healthy energy boost.
- Lipovitan's New Healthy Heart Formula contains a proprietary blend of energy sustaining vitamins with powerful antioxidants for your healthy heart.
- Metabolizes carbohydrates for energy **B**1
- Metabolizes carbs, fat & protein for energy B2
- Helps form antibodies **B6**
- Helps the body regulate cholesterol levels Taurine

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also see docket 975-0163 3878 Carson Street, Suite 216, Torrance, CA 90503 • Tel. (310) 543-2035 Fax 543-9636 Office of Nutritional Products, Labeling and Dietary Supplements Center for Food Safety and Applied Nutrition Food and Drug Administration February 28, 2003 Page 2

• Ginseng An herbal energy source

Royal Jelly Combats stress and fatigue

Niacin Converts food to energy

• Vitamin A Improves vision

• Vitamin C Helps the body regulate blood pressure

• Vitamin E Prevents breakdown of body tissue

• Grapeseed Extract Improves circulation and skin tone

• Lipovitan Healthy Heart Formula is no ordinary vitamin supplement. It provides a convenient, fast absorbing, healthy and effective energy boost while fighting oxidation and aging affects (effects) that damage your body.

• Lipovitan gives you Sustained Energy and Lasting Endurance!

I certify that the foregoing is complete and accurate, and that Taisho Pharmaceutical CA, Inc. has substantiation that the statements are truthful and not misleading.

Very truly yours,

Taisho Pharmaceutical CA, Inc.

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