

TAISHO PHARMACEUTICAL CALIFORNIA, INC.

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February 28, 2003

Via DHL

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

MAR 0 5 2003 BY:

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[®] Sustained Energy 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[®] Sustained Energy Formula

- Lipovitan is a healthy energy boost.
- Lipovitan's Original Energy Formula contains a proprietary blend of energy sustaining vitamins.
- **B**1 Metabolizes carbohydrates for energy
- B2 Metabolizes carbs, fat & protein for energy
- **B6** Helps form antibodies

DC: 777545-2

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al Se docket 975-0163 3878 Carson Street, Suite 216, Torrance, CA 90503 · Tel. (310) 543-2035 Fax 543-9636

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- Taurine Helps the body regulate cholesterol levels
- Ginseng An herbal energy source
- Royal Jelly Combats stress and fatigue
- Niacin Converts food to energy
- Lipovitan is no ordinary vitamin supplement. It provides a convenient, healthy and effective energy boost.
- Faster absorbing, and without the fillers used in tablet vitamin form, Lipovitan delivers healthy sustained energy in every bottle!
- 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.

by Scoff B. Slach