



MAR 19 2003 1392 '03 MAR 24 P1:52

Taisho Pharmaceutical California, Inc.
3878 Carson Street
Suite 216
Torrance, California 90503

Dear Sir:

This is in response to your letters of February 28, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Taisho Pharmaceutical California, Inc. is making the following claim for the products **Lipovitan® Sustained Energy Formula, Lipovitan® Healthy Joint Formula, and Lipovitan® Healthy Heart Formula.**

These products use the claim "Helps the body regulate cholesterol levels." In the preamble to the January 6, 2000 final rule on structure/function claims for dietary supplements (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The cholesterol claims for your products contain no such clarification, however. Therefore, FDA considers them to be implied claims to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for these products suggests that they are intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0103

LET 682

Page 2 - Taisho Pharmaceutical California, Inc.

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'SJW', is positioned above the typed name.

Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

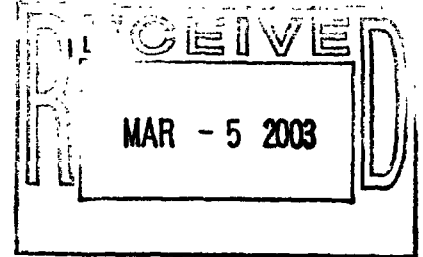
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



TAISHO PHARMACEUTICAL CALIFORNIA, INC.

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.
- B1 Metabolizes carbohydrates for energy
- B2 Metabolizes carbs, fat & protein for energy
- B6 Helps form antibodies
- Taurine Helps the body regulate cholesterol levels

DC: 777552-1

83665

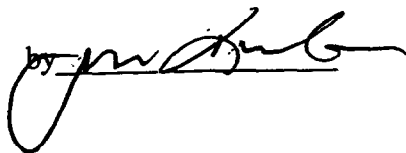
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
February 28, 2003
Page 2

- 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,

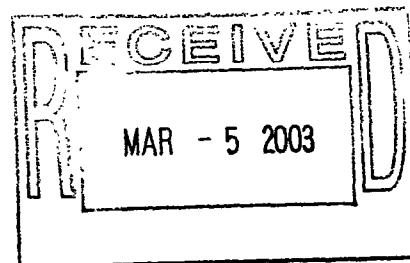
Taisho Pharmaceutical CA, Inc.





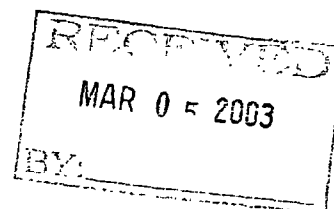
TAISHO PHARMACEUTICAL CALIFORNIA, INC.

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 Joint 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 Joint Formula

- Lipovitan is a healthy energy boost.
- Lipovitan's New Healthy Joint formula contains Lipovitan's proprietary blend of energy sustaining vitamins and glucosamine (1500mg) for overall joint health.
- B1 Metabolizes carbohydrates for energy
- B2 Metabolizes carbs, fat & protein for energy
- B6 Helps form antibodies
- Taurine Helps the body regulate cholesterol levels

DC: 777562-2

83665

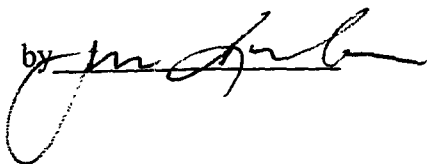
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
February 28, 2003
Page 2

- Ginseng An herbal energy source
- Royal Jelly Combats stress and fatigue
- Niacin Converts food to energy
- Glucosamine Helps maintain healthy joints
- Lipovitan Healthy Joint Formula is no ordinary vitamin supplement. It provides a convenient, fast absorbing, healthy and effective energy boost while naturally helping to maintain adequate cartilage in your joints
- 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 

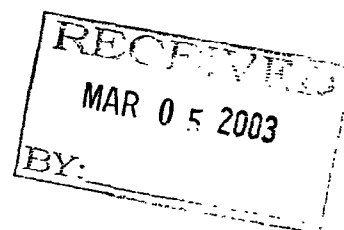


TAISHO PHARMACEUTICAL CALIFORNIA, INC.

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



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.
- B1 Metabolizes carbohydrates for energy
- B2 Metabolizes carbs, fat & protein for energy
- B6 Helps form antibodies

DC: 777545-2

83665

Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
February 28, 2003
Page 2

- 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 Jeff B. Slade