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APR 14 2003

Ms. Jeannie M. Perron, Esq.
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-2401

Dear Ms. Perron:

This is in response to your letter of April 2, 2003 to the Food and Drug Administration (FDA) on behalf of your client Taisho Pharmaceutical California, Inc., responding to our March 19, 2003 letter concerning claims being made for several of their products pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). In your letter, you included a revised claim for the product claim that we stated appeared to be disease claim that caused your client's products to be subject to regulation as drugs under the Act.

The revised claim you proposed for the products **Lipovitan® Sustained Energy Formula, Lipovitan® Healthy Joint Formula, and Lipovitan® Healthy Heart Formula** appears to resolve the issues we raised in our March 19, 2003 letter.

Please contact us if we may be of further assistance.

Sincerely yours,

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

975-0163

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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

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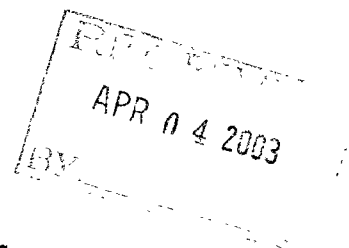
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April 2, 2003

BY FACSIMILE 301-436-2639

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
Department of Health & Human Services
Food and Drug Administration
College Park, Maryland 20740



Re: Your March 19, 2003 Letter to Taisho Pharmaceutical California, Inc.

Dear Dr. Walker:

I am responding to your letter of March 19, 2003 to my client Taisho Pharmaceutical California, Inc. regarding their letters pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act for the products Lipovitan® Sustained Energy Formula, Lipovitan® Healthy Joint Formula, and Lipovitan® Healthy Heart Formula.

You have objected to the claim "helps the body regulate cholesterol levels" on the labels of those products on the basis that the statement lacks the clarification that the product helps regulate cholesterol that is already within the normal range. Although we do not agree with the interpretation of the claim "helps the body regulate cholesterol levels" as stated in your letter and reserve all rights with respect thereto, in the interest of settling this matter in the most expedient manner possible, we will agree to insert the phrase "which are already within the normal range" into that claim on the next label printing. Therefore, the new labels would each contain the claim:

"Taurine Helps the body regulate cholesterol levels which are already within the normal range."

If this amended language meets with your approval, please so advise me as soon as possible. My email address is jperron@cov.com.

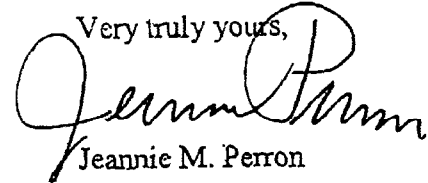
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Susan J. Walker, M.D.
April 2, 2003
Page 2

Your assistance is sincerely appreciated.

Very truly yours,

A handwritten signature in cursive script, appearing to read "Jeannie M. Perron". The signature is written in black ink and is positioned above the printed name.

Jeannie M. Perron

cc: Eugene Lambert, Esq.