



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR - 3 2007

Mr. Benjamin England
Jones, Walker, Waechter, Poitevent,
Carrere & Denegre LLP
The Watergate
2600 Virginia Avenue, N.W., Suite 1113
Washington, DC 20037

Dear Mr. England:

This is in response to your letter of March 23, 2007 to the Food and Drug Administration (FDA), on behalf of your client Lativio, LLP, 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 Lativio LLP is making the following claims, among others, for the product **Proactol™** :

“Helps reduce Blood Cholesterol.”

“Lowering Cholesterol.”

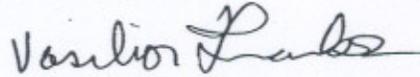
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that your client is making for this product suggest that it is intended to treat, prevent, or mitigate diseases (i.e., hypercholesterolemia). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If your client intends to make claims of this nature, they should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

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Please contact us if we may be of further assistance.

Sincerely yours,



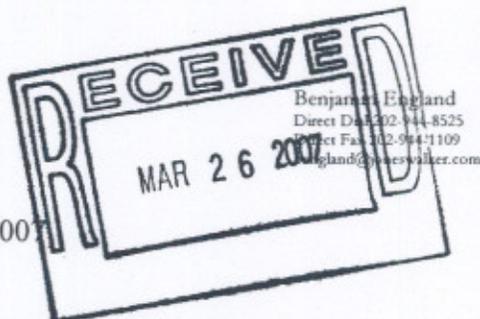
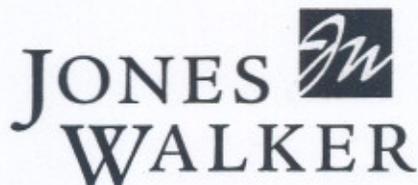
Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

Copy:

Lativio LLP
Park Lane Business Centre
Old Basford
Nottingham, NG6 0DU, England



March 23, 2007

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

Re: Lativio's Notification of Structure and Function Claims for Proactol™, Under 21 C.F.R. 101.93.

Dear Sir or Madame:

We represent Lativio, LLP. Please find attached an original and three copies of a notification of structure and function claims for Proactol™, pursuant to 21 C.F.R. §101.93(r), which we submit to you on behalf of Lativio, LLP.

We also ask you to kindly sign and date stamp one of the three copies of the notification and return that signed and date-stamped copy to my attention as evidence of our filing of this notification. You may use the enclosed self addressed stamped envelope to return the date-stamped and signed copy.

If you have any questions, please do not hesitate to contact me directly. I can be reached at 202-944-8525 (office), 443-538-1940 (cell), or bengland@joneswalker.com.

Sincerely,

Handwritten signature of Benjamin England

Benjamin England

BLE/mge

(WD003160.1)

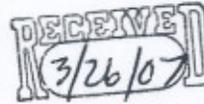
JONES, WALKER, WAECHTER, POITEVENT, CARRÈRE & DENÈGRE L.L.P

THE WATERGATE 2600 VIRGINIA AVENUE, N.W. SUITE 1113 WASHINGTON, D.C. 20037
202-944-1100 FAX 202-944-1109 E-MAIL info@joneswalker.com www.joneswalker.com

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2007-1982



Lativio LLP
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Park Lane Business Centre
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Nottingham
NG6 0DU
UK

Contact: Darren Beale
Tel: (+44) 0115 9798418 EXT 208
Fax: +44 (0) 115 9798424
Email: Darren@Lativio.com

March 19, 2007

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

Re: **Notification of Structure and Function Claims for Proactol™ Under 21 C.F.R. 101.93**

Dear Sir/Madam:

Pursuant to 21 CFR 101.93, Lativio LLP, hereby notifies you that it has included structure and function claims for its dietary supplement Proactol™ in its labeling. This notice is provided in compliance with regulations promulgated and enforced by the U.S. Food and Drug Administration. Lativio LLP, intends to fully comply with all FDA requirements respecting the labeling, marketing and distribution of its dietary supplements. If you have any concerns regarding this notice or its contents, please contact the undersigned immediately.

Lativio LLP, is the distributor for Proactol™ and its address and contact information are as follows:

Lativio LLP
Park Lane Business Centre
Old Basford
Nottingham, NG6 0DU, England
Phone: +44 (0) 115 979 8418

Structure or function, or general health and well being claims made for Proactol™:

1. "Proactol™ is a clinically tested fat binder"
2. "The results of . . . clinical studies show that by taking Proactol™ you can expect to:
Bind Up to 28% of Dietary Fat Intake; Reduce Your Calorie Intake; Help Reduce Excess Body Weight."
3. "[Proactol™] Helps Reduce Food Cravings; Helps Reduce Blood Cholesterol; Helps Decrease Your Appetite"

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4. "Proactol™ can help you achieve a much healthier lifestyle."
5. "When Proactol™ non-soluble fibres come into contact with dietary fats, it binds with them immediately to form a fluid gel around the fat making it insoluble. Unabsorbed fats then pass naturally through your body. Proactol™ has been clinically tested to bind up to 28% of dietary foods."
6. "Proactol™ soluble fibres are highly viscous when they bind with bile acids to create a very viscous solution, which slows down digestion and slows down the absorption of glucose. This will suppress your appetite and food cravings."
7. "[S]tudies showed that the [study] volunteers taking Proactol's active ingredients bound an average of 27% more dietary fat when compared to the group taking a placebo. Extensive research has shown that a reduction in dietary fat intake contributes to weight loss."
8. "[B]y [using] Proactol™ [as instructed in its label] you will be able to achieve your weight loss goals [and] a healthier lifestyle and look . . ."
9. "Taken after food, Proactol™, made of non-soluble and soluble fibres, immediately attaches to fats found floating around on the surface of the stomach. This creates a fat-fibre complex that is too large to be absorbed in the small intestine, allowing fat to pass naturally through the body."
10. "Proactol™ offers a healthy way of making it easier to take charge of your weight and eating habits, whilst also addressing issues beyond weight management, such as lowering cholesterol and balancing blood glucose fluctuations."

Proactol™ Ingredients

The ingredients of Proactol™ are:

- *Opuntia ficus-indica* fiber complex (granulated)
- Microcrystalline cellulose
- Calcium hydrogen phosphate dihydrate
- Silica
- Povidone

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- Magnesium stearate

Certification

Darren Beale, Managing Partner of Lativio LLP, hereby certifies that the information presented and contained in this Notice is complete and accurate respecting structure and function claims made on the label or in the labeling of Proactol™ and that Lativio, LLP, has substantiation that each statement is truthful and not misleading.

Darren Beale

D. C. Beale

Date: 19/03/07

Encl. two copies attached