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Mr. Benjamin England, Esq.
Jones, Walker, Waechter, Poitevent,
Carrere & Denegre L.L.P.
2600 Virginia Avenue, N.W.
Suite 1113
Washington, D.C. 20037-1992

Dear Mr. England:

This is in response to your letter to the Food and Drug Administration (FDA) dated November 22, 2006 (received by FDA May 1, 2007) on behalf of your client Lativio LLP, Nottingham, England. Your letter responded to FDA's letter of April 3, 2007 that addressed claims contained in a notification submitted to FDA 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 stated that the firm intended to amend the claims contained in the original notification to:

“Helps manage blood cholesterol” and
Helps “to maintain healthy cholesterol levels.”

In the preamble to the January 6, 2000 final rule on structure/function claims (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. Because the claims your client proposes to use for this product represent that the product is intended to affect blood cholesterol but do not expressly include a statement that the product is intended to affect blood cholesterol that is already in the normal range, these claims continue to appear to be implied disease claims.

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Page 2 - Mr. Benjamin England, Esq.

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 disease. 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 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

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:

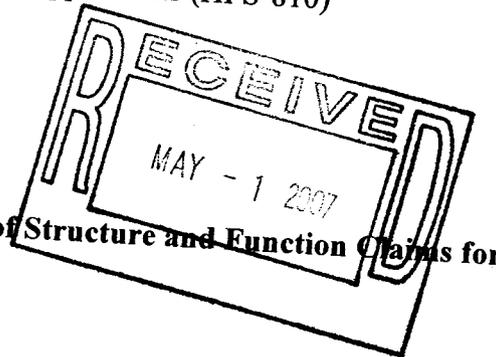
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200



Benjamin England
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Direct Fax 202-944-1109
benjand@joneswalker.com

November 22, 2006

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 LLP's Amended 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 an amended 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.

This amended notification is being filed in response to your letter, dated April 3, 2007 in which you object to claims for Proactol™ stating that it:

- "Helps reduce Blood Cholesterol" and
- Helps in "Lowering Cholesterol."

In the attached amended notification, these claims are reworded to state that Proactol™:

- "Helps manage blood cholesterol" and
- Helps "to maintain healthy cholesterol levels."

We 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 to us.

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

601 BRICKELL KEY DRIVE SUITE 500 MIAMI, FL 33131 305-679-5700 FAX 305-679-5710 E-MAIL info@joneswalker.com www.joneswalker.com

BATON ROUGE HOUSTON LAFAYETTE MIAMI NEW ORLEANS WASHINGTON, D.C.

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Proactol™

April 25, 2007

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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.

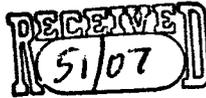
Sincerely,



Benjamin England

Cc: D. Beale, Lativio, LLP
File

BLE/mge



Lativio LLP
Unit 3A
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NG6 0DU
UK

Contact: Darren Beale
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Email: Darren@Lativio.com

April 17, 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:

In response to the Agency's letter of April 3, 2007, Lativio, LLP is submitting this revised notification of structure and function claims for its dietary supplement Proactol™ in its labeling pursuant to 21 CFR 101.93. 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 revised 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

CFSAN, ONPLDS; HFS-810

Section 101.93 Structure/Function Claim Notification: Proactol™

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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 manage blood cholesterol; Helps Decrease Your Appetite"
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 helping to maintain healthy cholesterol levels and balancing blood glucose fluctuations."

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Section 101.93 Structure/Function Claim Notification: Proactol™

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Proactol™ Ingredients

The ingredients of Proactol™ are:

- *Opuntia ficus-indica* fiber complex (granulated)
- Microcrystalline cellulose
- Calcium hydrogen phosphate dihydrate
- Silica
- Povidone
- 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: 17/04/07

Encl. two copies attached