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JUL 31 2002

Ms. Evelyn Poon  
Marketing Consultant  
Country Life  
180 Vanderbilt Motor Parkway  
Hauppauge, New York 11788

Dear Ms. Poon:

This is in response to your letters of June 28, 2002 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)).

The product Cholesterin uses the claims "Natural Cholesterol Blocker," "Cholesterin - the Better Way to Beat Cholesterol," "Nutritional Support for Borderline Cholesterol," "CHOLESTERIN is the best way to naturally help maintain healthy cholesterol levels," "Cholesterin is the natural choice for healthy cholesterol management." The product Cholesterin Plus uses the claims "Natural Cholesterol Blocker," "Lowers LDL Cholesterol up to 21%. Improves HDL/LDL ration by as much as 63%," "...cholesterol formula," "CHOLESTERIN PLUS has Non-Flush Niacin which supports healthy cholesterol levels and healthy ratios of LDL (bad) cholesterol..," "Only CHOLESTERIN PLUS combines...which both lowers LDL (bad) cholesterol..." "...fosters support for healthy cholesterol levels and healthy ratios of LDL (bad) cholesterol..." 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. The claims for your products do not establish that the claims are about blood cholesterol levels that are already within normal limits and, therefore, imply that the product is intended to treat elevated blood cholesterol levels and reduce the **risk** of a disease, namely, coronary heart disease. Moreover, in the preamble to the January 6, 2000 final rule, FDA stated that a claim that a product "lowers cholesterol, however qualified, is an implied disease claim. Several claims clearly establish that these products are intended to lower elevated cholesterol (e.g., "Lowers LDL Cholesterol..." and "...the Better Way to Beat Cholesterol").

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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 you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "John B. Foret". The signature is written in a cursive style with a long horizontal stroke at the end.

John B. Foret  
Director  
Division of Compliance and Enforcement  
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

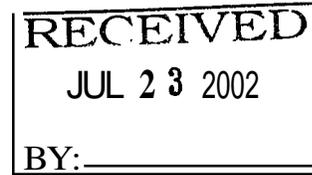
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140



Partners in Health and Beauty

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835



June 28, 2002

This letter serves as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA), that Country Life® is using the following statements on the label of Cholesterin™ tablets (dietary ingredient: alfalfa extract). These statements are accompanied by the required disclaimer. To the best of my knowledge, the information contained in this notice is complete and accurate.

Natural Cholesterol Blocker.

Blocks cholesterol in the stomach before it reaches the liver.

Cholesterin – the Better Way to Beat Cholesterol.

Nutritional Support for Borderline Cholesterol.

Unlike other formulas which work in the liver, CHOLESTEFUN is the first and ONLY scientifically proven formula which BLOCKS (or binds with) *new* cholesterol from the food you eat while simultaneously enabling your body to naturally excrete *old* cholesterol. CHOLESTERIN is the best way to naturally help maintain healthy cholesterol levels.

CHOLESTERIN works by binding with *new* cholesterol in your STOMACH before it reaches the liver. CHOLESTERIN is the best way to naturally help maintain healthy cholesterol levels.

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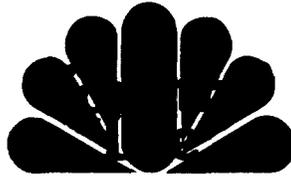
Cholesterin is the natural choice for healthy cholesterol management. The active ingredient in Cholesterin is Esterin Process Saponins derived from natural alfalfa via an exclusive, patented extraction process invented in 1990.

This ecologically friendly water and alcohol extraction process utilizes the leaf of the plant that provides the highly concentrated alfalfa derived saponins used to naturally control cholesterol.

Sincerely,

A handwritten signature in cursive script that reads "Evelyn Poon".

Evelyn Poon  
Marketing Consultant **M.B.A.**



*Partners in Health and Beauty*

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
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5100 Paint Branch Parkway  
College Park, MD 20740-3835



June 28, 2002

This letter serves as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA), that Country Life® is using the following statements on the label of Cholesterin Plus™ tablets (dietary ingredients: alfalfa extract, niacin, inositol). These statements are accompanied by the required disclaimer. To the best of my knowledge, the information contained in this notice is complete and accurate.

Natural Cholesterol Blocker.

Lowers LDL Cholesterol up to **21%**. Improves HDL/LDL ratio by as much as **63%**.

Maximum Strength Cholesterol Formula.

Cholesterin Plus with Niacin formulated to help fight cholesterol!

CHOLESTERIN PLUS has Non-Flush Niacin which supports healthy cholesterol levels and healthy ratios of LDL (bad) cholesterol and HDL (good) cholesterol. Unlike standard forms of Niacin, which may cause undesirable side effects, CHOLESTERIN PLUS is uniquely formulated with Non-Flushing Inositol Hexanicotinate - the safest form of Niacin.

Unlike other formulas which work in the liver, CHOLESTERIN PLUS is the first and ONLY scientifically proven formula which BLOCKS (or binds with) new cholesterol from the food you eat while simultaneously enabling your body to naturally excrete the *old* cholesterol.

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Only CHOLESTERIN PLUS combines the strength of Esterin® Alfalfa Saponin Extract with the power of Niacin which both lowers LDL (bad) cholesterol, while also improves HDL (good) cholesterol.

Unlike standard forms of Niacin, which may cause undesirable side effects, CHOLESTERIN **PLUS** is uniquely formulated with Non-Flushing Inositol Hexanicotinate - a safe form of Niacin. Its sustained metabolism lasts for up to ten hours after digestion and fosters support for healthy cholesterol levels and healthy ratios of LDL (bad) cholesterol and HDL (good) cholesterol.

Sincerely,

A handwritten signature in black ink, appearing to read "Evelyn Poon".

Evelyn Poon  
Marketing Consultant **M.B.A.**