DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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AUG - 2 2001

Ms. Cindy Nydell
Tabak's Health Products
3198 Airport Loop Drive
Suite G
Costa Mesa, California 92626

Dear Ms. Nydell:

This is in response to your letter of June 15, 2001 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 Tabak's Health Products is marketing the product **CholestLo**, which contains the ingredient Red Yeast Extract and that this ingredient is standardized to contain not less than 0.4% lovastatin. This letter is to advise you of the current legal status of products that contain red yeast rice containing lovastatin.

FDA announced its administrative decision on May 20, 1998 that a product named "Cholestin[1]", manufactured by Pharmanex, Inc., which was promoted as a dietary supplement intended to affect cholesterol levels, is not a dietary supplement, but is instead an unapproved drug under the Act. This decision meant that Cholestin could not be legally sold in the United States.

A February 16, 1999 United States District Court for the District of Utah decision that "held unlawful and set aside" the FDA's May 20, 1998 decision was reversed by a United States Court of Appeals for the 10th Circuit decision on July 21, 2000. This reversal reinstates FDA's administrative decision that Cholestin is a drug, not a dietary supplement. The reversal also remanded the case back to the District Court for consideration of record-based issues not previously reached by the lower court in its original decision. On March 30, 2001, the United States District Court for the District of

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[1]Cholestin consists of the yeast *Monascus purpureus* when fermented on premium rice powder. The fermentation of the rice with this yeast, under certain conditions, produces a product that contains lovastatin, the active ingredient in the prescription cholesterol-lowering drug Mevacor.

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Utah issued a Memorandum Decision and Order on the remaining record-based issues. The District Court affirmed the FDA's administrative decision that Cholestin is a drug, not a dietary supplement. Taken together, the courts' decisions in the Pharmanex litigation mean that red yeast rice or similar products containing lovastatin are unapproved new drugs in violation of the Act. Marketing of a product that is in violation of the Act may result in enforcement action being initiated by FDA without further notice. Among other remedies, the Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Your submission also states that you are making the following claims, among others, for the following products:

CholestLo

> "...keeps your cholesterol levels in check..."
> "Keep your cholesterol levels healthy"
> "Helps keep cholesterol levels in the normal range"
> "Maintain healthy cholesterol levels"
> "Keep your LDL and total cholesterol in a healthy range"

BoneKeeper

> "It can and should be combined with Arthritis-Ease, the homeopathic remedy to relieve pain, stiffness, inflammation and tenderness in joints."

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 diseases, namely hypercholesterolemia and arthritis. 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 you require further assistance.

Sincerely,

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

Tabak's
HEALTH PRODUCTS
A Corporation

Our Guiding Philosophy:
Superior, *Science-Based*
Nutritional Supplements

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JUN 18 2001

June 15, 2001

Mr. Robert Moore
Food and Drug Administration
200 C. Street SW
Washington, DC 20204

Dear Mr. Moore,

In compliance with the final ruling for Dietary Supplements dated January 6, 2000 here are copies of our offers for your files:

Sincerely,

Cindy Nydell

Cindy Nydell

Enclosures

P-9001

3198 Airport Loop Drive Suite G • Costa Mesa, CA 92626 • Ph. (714) 850-1007 • Fax (714) 850-1020 • Email: info@tabaks.com • Website: www.tabaks.com

I, Lawrence Tabak, certify the accuracy of the information presented and contained in the notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

To the best of my knowledge and belief, I believe the above is true.

Lawrence Tabak,
President

With Your BoneKeeper™

Dear friend,

You've made a wise decision by sending for BoneKeeper™. Why? The answer is simple. BoneKeeper™ is a highly advanced calcium supplement based on the proven ingredient, microcrystalline hydroxyapatite (MCHC).

Two tablets of BoneKeeper™ contain:

Calcium (as microcrystalline hydroxyapatite and dicalcium phosphate) 440mg

Phosphorus 280mg

Microcrystalline Hydroxyapatite 1,000mg

Glucosamine Sulfate . . . 50mg

BoneKeeper™ contains a unique combination of co-factors specially formulated to support healthy bone formation.

Here's what you get in BoneKeeper™:

1) Glucosamine Sulfate gives you nutritional support to help maintain healthy joints and synovial fluid.[1]

2) Many of the same materials naturally found in your bones, such as zinc, copper, maganese are combined in BoneKeeper™.

MCHC Is A Potent Nourishing Agent For Your Bones!

Without sufficient calcium and minerals, your bones simply become weak and brittle. The good news is that MCHC supplies you with a natural form of calcium and these essential minerals . . .

What is MCHC, you ask? Microcrystalline hydroxyapatite (MCHC) is an extract from whole bone. It is a rich source of calcium minerals and organic factors that are present in healthy bones. A link has been set between calcium deficiency and the onset of osteoporosis.

How can you avoid this? Or help reverse this trend if it's already begun?

Spur Your Body to Maintain Strong Bones!

And that's exactly what the ingredients in BoneKeeper™ do. They supply the co-factors you need . . . to maintain strong bones.[2,3,4]

Friendly, knowledgeable customer service is a top priority at Tabak's Health Products.

Scientific studies show the value of MCHC and healthy bones. Best yet, MCHC is the key ingredient you'll find in your supply of BoneKeeper™.

BoneKeeper™ is the perfect calcium supplement to take every day for optimal healthy bones. It contains no sugar, yeast or starch. Nothing artificial.

It's completely natural. And effective.

It can and should be combined with Arthritis-Ease®, the homeopathic remedy to relieve pain, stiffness, inflammation and tenderness in joints. Arthritis-Ease® is available from Tabak's Health Products.

Keep Your Cholesterol Healthy

Dear friend,

You've made a wise decision by sending for CholestLo™. Why? The answer is simple. CholestLo™ contains these proven ingredients:

Red Yeast Rice: Studies of traditional Chinese medicine, Western biochemistry and modern pharmacology all have helped identify Red Yeast Rice (and its components) as a beneficial and important dietary supplement for maintaining healthy cholesterol levels. Those effects have been rigorously examined, tested, and evaluated.

During research, it was liscovered that Red Yeast Rice :ontained beneficial ngredients, including naturally ccurring HMG CoA reductase nhibitors (material that egulates production of holesterol).[1]

It was found that these inhibitors actually help promote healthy cholesterol levels.

here have been more than clinical studies in China l the U.S., each measuring nges in total cholesterol, triglycerides, and HDL cholesterol.

A study conducted at the UCLA School of Medicine confirmed that Red Yeast Rice, taken orally, maintained healthy cholesterol levels effectively with little or no adverse effects.[2] Little wonder why this natural ingredient is attracting such merited attention.

Studies show Beta-1, 3-D Glucan supports cholesterol levels in a healthy range.[3]

Beta-1, 3-D Glucan, an important derivative of oat fibre, was shown to be effective in supporting healthy levels of total and LDL cholesterol, as reported in The American Journal of Clinical Nutrition.[4]

The beneficial effect of beta-glucans are well documented.

Niacin: Over the past 45 years, an avalanche of scientific reports have provided convincing evidence that niacin can be a safe and effective way to maintain cholesterol levels within the normal range. In fact, it's been

Friendly, knowledgeable customer service is a top priority at Tabak's Health Products.

proven to maintain and support normal levels of both LDL, or "bad" cholesterol and HDL, or "good" cholesterol.[5]

There you have it. Point blank evidence that these ingredients actually promote healthy cholesterol levels! The good news is . . . CholestLo™ contains all of them - and more! Now put these proven ingredients to work for you - beginning today!

Suggested Dosage

Take one tablet twice daily with meals.

The key to maintaining healthy cholesterol levels with CholestLo™? Take it regularly. Make it part of your daily regimen along with a healthy diet and exercise.

Do get started now.

se statements have not been evaluated by the Food and Drug Administration. This

Superior, Science-Based Nutritional Supplements

Some people wonder how Tabak's Health Products - which started just eight years ago - became a *leading* direct marketer of nutritional supplements.

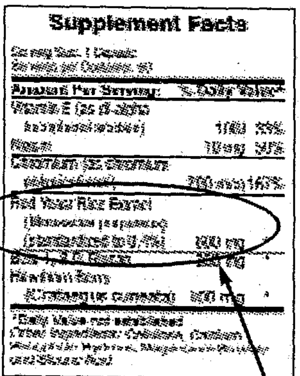
Actually, the answer is quite simple. It's because of our core belief that, above all else, we must provide **superior, science-based nutritional supplements, that improve the quality of your life**.

Take Red Yeast Rice powder, the main ingredient in our CholestLo™ product, as a prime example.

Clinical tests using Red Yeast Rice powder, standardized to .4% showed that it supports healthy cholesterol levels.

Powder not standardized like this simply won't work. Ours, on the other hand, which *is* standardized to .4%, produces the desired effect!

What we do in our research department is select ingredients for our formulas that are *based on science.*



In the example above, note how the certificate of analysis - that we insist on receiving - confirms the ingredient meets our standards.

This means we search for clinical studies that show how an ingredient actually affects the structure or function of your body in a beneficial way.

We dig further to see what daily dose was used in the study.

We look at the specification or standardization of the ingredient.

Then, when we order our raw materials, we insist on receiving a Certificate of Analysis to verify it meets our standards. (See the example below.)

More importantly, the ingredients we select are based on science - *not* on cost. We are not interested in making cheap products. Instead, we create superior formulas that can enhance your health and improve the quality of your life!

When it comes to your body and your health, believe us, *you want the best.*

Our pledge to you

You get superior, science-based formulas.

Plus, the ingredients are supported by clinical trials proving how they affect the structure and function of your body in a positive way.

The bottom line? Our formulas can *actually* enhance your health and impact your life, like never before! Therefore, they are worth *far more* than the small amount we ask for them! You have our word on it!

CERTIFICATE OF ANALYSIS

PRODUCT: RED YEAST RICE EXTRACT 0.4%
LOT NUMBER: 145495

ITEM	SPECIFICATION	RESULT
SPECIES:	Monascus purpurea	CONFORMS
APPEARANCE:	POWDER	CONFORMS
COLOR:	RED TO DARK RED	CONFORMS
ODOR:	TYPICAL	CONFORMS
TASTE:	CHARACTERISTIC	CONFORMS
MOISTURE:	NOT MORE THAN 8.0%	3.5%
(CSC MOISTURE 56 @ 65 TEMP)		
~~CARRIER:~~	~~TERRA ALBA~~	CONFORMS
LOVASTATIN:	NOT LESS THAN 0.4%	0.45%
~~(HPLC)~~		

Date: April 19, 1999 QUALITY CONTROL 4012

EXAMPLE

Supporting References

1. Heber D. "Herbs and atherosclerosis." Current Atherosclerotic Report 2001 Jan;3(1):93-6.
2. Heber D, et al. "Cholesterol-lowering effects of a proprietary Chinese red-yeast-rice dietary supplement." American Journal of Clinical Nutrition 1999 Feb;69(2):231-6.
3. Bell S, et al. "Effect of beta-glucan from oats and yeast on serum lipids." Crit Rev Food Sci Nutr 1999 Mar;39(2):189-202.
4. Brown L, et al. "Cholesterol-lowering effects of dietary fiber: a meta-analysis." American Journal of Clinical Nutrition 1999 Jan;69(1):30-42.
5. Capuzzi DM, et al. "Niacin dosing: relationship to benefits and adverse effects." Current Atherosclerotic Report 2000 Jan;2(1):64-71.

This product is not intended to diagnose, treat, cure, or prevent a disease, but rather is a dietary supplement intended solely for nutritional support. These statements have not been evaluated by the Food and Drug Administration. The ingredients in CholestLo™ have been proven to promote healthy cholesterol levels, but in no way is CholestLo™ intended to replace or be a substitute for any prescribed cholesterol related medications.

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3198 Airport Loop Drive, Suite G · Costa Mesa, CA 92626

www.tabaks.com