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## URGENT DIETARY SUPPLEMENT RECALL

February 8, 2002

Dear Customer:

I am writing to inform you of the results of certain recent laboratory tests conducted by the California Department of Health Services ("DHS"). DHS' testing discovered a compound called Warfarin, a synthetic blood thinner, in samples of our product **PC SPES**. Warfarin is the generic name for Coumadin, a pharmaceutical agent used by many doctors in the prevention and/or treatment of blood clots, pulmonary embolisms, and thromboembolic complications associated with cardiac valve replacement and atrial fibrillation. As a result, DHS asked BotanicLab to issue a product recall for PC SPES.

BotanicLab also conducted independent testing of the product, and based on the advice of its experts believes further analysis and testing is needed. In addition to their own testing, these experts cite evidence in the scientific literature for their view that further testing is necessary to confirm the material at issue is Warfarin.

However, BotanicLab believes our first responsibility is to the safety and well being of our customers. Therefore, we are taking two prudent steps. First, we accept the DHS request and are issuing this **Product Recall of ALL LOTS of PC SPES**.

If you have any quantities of PC SPES, please discontinue their use immediately and return the product in its original packaging to us for a full refund.

Please return the product to:  
PC SPES Recall Program  
2900-B Saturn Street  
Brea, CA 92821  
1-800-458-5854

Second, we are also undertaking additional testing of PC SPES in both commercial and academic laboratories to gain more insight into the material at issue. We intend to share the results of these tests with DHS, as well as with our customers, as soon as they are available.

As we implement a new quality control process, further shipments of PC SPES may not be immediately available. We understand the seriousness of this issue and sincerely apologize for not meeting your PC SPES needs at this time. We want you to know that we are doing everything we can to resume shipments as soon as possible.

For more information, please contact our toll-free hotline, **1-800-458-5854**.

Sincerely,

John Chen  
President & CEO  
BotanicLab

*P.S. On the reverse side of this letter, please find "Questions and Answers: PC SPES Testing," which provides more detailed information. If you have additional questions not addressed on this sheet, please call our toll-free hotline, 1-800-458-5854.*

**A note to distributors, retailers and health care professionals:  
Please forward a copy of this notification to your customers, clients and patients.**

### **QUESTIONS AND ANSWERS: PC SPES TESTING**

#### **What is Warfarin and how is it used?**

Warfarin is the generic name for COUMADIN®, a pharmaceutical agent used by many doctors in the prevention and/or treatment of blood clots, pulmonary embolisms, and thromboembolic complications associated with cardiac valve replacement and atrial fibrillation. The 2001 Edition of the Physician's Desk Reference (PDR) identifies 2-10 milligrams per day of Warfarin as a satisfactory maintenance dosage for most patients. COUMADIN® interacts with many drugs, including prescription and non-prescription (over-the-counter) drugs. Some of the non-prescription drugs that may interact with COUMADIN® include: acetaminophen (\*\*Tylenol®); aspirin and aspirin-containing ointments and skin cremes; ibuprofen (\*\*Motrin®, \*\*Advil®, \*\*Nuprin®); naproxen (\*\*Aleve®, \*\*Orudis KT®); H2-receptor antagonists, such as cimetidine (\*\*Tagamet®) or ranitidine (\*\*Zantac®); and vitamin supplements containing vitamin K. Other drugs may affect your response to COUMADIN®. Please check with your healthcare provider for additional information.

#### **What are the side effects of Warfarin?**

The main side effect of Warfarin is bleeding; patients who are maintained at a therapeutic level will not normally bleed spontaneously. Warfarin also can interact with other medications, including aspirin and other inflammatory or pain medicines, antibiotics and antifungals, thyroid drugs, antidepressants and cholesterol-lowering drugs. Nosebleeds that cannot be stopped with pressure within ten minutes, gums that bleed even after repeated rinsing with cold water, blood in the sputum, urine or stool should be discussed with your physician. Other symptoms that should be discussed immediately with a physician include unexplained, sharp and sudden headaches, visual changes, numbness and tingling in the arms or legs or persistent pain or swelling. BotanicLab provides this information for you to share with your own health care professional and recommends you consult him or her on these matters.

#### **How was Warfarin discovered in PC SPES?**

Several lots of PC SPES were tested by DHS for the presence of drugs, including Warfarin. No other drug finding was reported to BotanicLab by DHS.

#### **What is the level of Warfarin that DHS found in PC SPES?**

The highest level of Warfarin that DHS found in one capsule of PC SPES was 0.211 milligrams. Recommended dosage for PC SPES (as identified on the product label) is 3 capsules in the morning, and for additional benefit, another 3 capsules in the evening. If a user consumed the maximum recommended 6 capsules per day of PC SPES, the amount of Warfarin ingested per day would be 1.27 milligrams, which is approximately 63% of the lowest maintenance dosage recommended by the PDR.

**BotanicLab believes further testing of PC SPES is needed.**

Our independent lab experts believe the material in question may not be Warfarin, but may instead be a phytocoumarin (a compound naturally synthesized in various green plants) that may "mimic" Warfarin in laboratory testing. The sensitivity of various testing equipment and testing protocols affects the ability of a test to accurately analyze the complex organic substances contained in any botanical product. Naturally occurring organic compounds can occasionally mimic other substances unless additional testing measures are used. In these circumstances, BotanicLab believes the additional testing measures recommended by their independent, third-party testing experts will indeed be more sensitive and thus hopefully provide more definitive information and results.

**What is BotanicLab doing to minimize the risk of drugs in PC SPES?**

We have undertaken a process to establish more rigorous controls throughout the entire production process, starting with raw materials we purchase from a number of suppliers in China. The exacting controls we establish will ensure our suppliers adhere to the same quality standards we follow throughout the blending, packaging and shipping process. We have also contracted with world-class research laboratories and universities to assist in implementing our more stringent testing.

**How do I return any product I may have?**

Please return product in a padded mailing envelope. Opened bottles should be placed in a Ziploc bag or other wrapper to prevent spillage before placement in a padded mailing envelope. Unopened bottles can be placed directly in a padded mailing envelope. Please return the product to:

PC SPES Recall Program  
2900-B Saturn Street  
Brea, CA 92821  
1-800-458-5854

BotanicLab will issue a prompt, full refund to you upon return of the product. If you have additional questions not addressed on this sheet, please call our toll-free hotline, 1-800-458-5854.

**How soon will PC SPES be available?**

Raw materials for the next lot of PC SPES are currently being tested. Assuming the results of these tests prove favorable, we would anticipate shipping PC SPES as soon as possible. We sincerely apologize for not meeting your PC SPES needs, but for everyone's sake, any quality issues must be addressed before additional product can be released.

[Click here to read more about the BotanicLab recall](#)

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