Dynamic Chiropractic

VITAMINS / SUPPLEMENTS

FDA Recalls Two Prostate Supplements

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Since January 9, 2002, the United States Food and Drug Administration (FDA) has issued a recall of two commercially available prostate supplement products. The *FDA Enforcement Report* is published weekly by the U.S. Department of Health and Human Services. It contains information on actions taken in connection with agency regulatory activities. On January 9, 2002, the FDA issued recall #F-110-2 of the product, "Prostatin Formula #103," dispensed in 30 and 90-capsule bottles of 500-mg capsules. The reason for the recall was that this product contained aristolochic acid, a known potent carcinogen and nephrotoxin. This product is manufactured in Taiwan by Sheng Chang Pharmaceutical Co., Ltd., and is available in the U.S. under the Herbal Doctor Remedies brand, (Monterey Park, California).

On March 2, 2002, the FDA issued a class II recall of the prostate supplement known as PC-SPES, and SPES capsules, because they were shown to contain the drugs warfarin and alprazolam, respectively. A class II recall indicates that exposure to a violative product may cause temporary or medically reversible adverse health consequences, but the probability of serious adverse health consequences is remote. In the case of PC-SPES and SPES capsules, they contained undeclared prescription drug ingredients that could cause serious health effects if not taken under medical supervision. On May 1, 2002, the enforcement report declared that PC-SPES was now a class I recall, which indicates that there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

In a related document, online news supplier Reuters Health reported that researchers confirmed the presence of the blood thinner warfarin and the anti-inflammatory drug indomethacin in samples of PC-SPES, as presented at the 93rd annual meeting on the American Association for Cancer Research. It also indicated that the potent estrogenic drug diethylstilbesterol (DES) was detected in PC-SPES. DES is known as the drug that was given to pregnant women, and later resulted in serious reproductive abnormalities in their daughters, including increased risk of uterine cancer. PC-SPES and SPES are products distributed by International Medical Research, dba Botanic Labs, Inc., in Brea, California. The recall numbers are D-196-2 for SPES capsules and D-198-2 for PC-SPES capsules.

The FDA has recalled an additional seven herbal products from Botanic Labs in the U.S. and abroad as a class II recall, as reported on August 7, 2002. These include:

- RA-SPES joint and tendon formula - 30 capsules, 300 mg each;
- OA-Plus joint and tendon formula - 30 capsules, 300 mg each;
- Hepastat liver formula - 90 capsules, 300 mg each;
- Neutralis immune system formula - 30 capsules, 300 mg each;
- Osporo skeletal formula - 30 capsules, 300 mg each;
- Poena muscle and tissue formula - 30 capsules, 300 mg each; and
- Arthrin joint and tendon formula - 30 capsules, 300 mg each.

Once again, the reason for the recall is that these products have been shown to contain various amounts and combinations of undeclared prescription drug ingredients, including alprazolam, indomethacin, ethinyl estradiol and/or DES.

These recalls are a good illustration why health practitioners should recommend only those supplements whose manufacturers are able to verify via third-party testing (not in-house post-production testing) that the recommended products contain what the labels indicate, and that no adulteration by drugs or other substances has occurred in the manufacturing of the products. Due to the inadequate standards that govern the manufacturing and distribution of dietary supplements in the U.S. and Canada, health practitioners should ensure that the products they recommend or dispense to patients have their purity and potency verified through third-party testing. Documents of this nature are available upon request from the manufacturers of the products.

I strongly suggest that you request this information prior to recommending a product, no matter how good its reputation is in the marketplace, as some of the most reputable supplement companies have failed third-party testing in recent years.

To keep you abreast of the latest recalls and warnings in the area of food, drugs (including supplements), biologics and health devices, the FDA's weekly enforcement report can be accessed at www.fda.gov/bbs/topics/enforce/2002/ENF00755.html.

Please take time to listen to Dr. Meschino's interviews at www.chiroweb.com/audio/meschino. The subjects of the first three are: *Combining Traditional, Complementary and Natural Intervention, The Benefits of Melatonin, and Using Natural Remedies to Manage Women's Health Issues*. Each interview is packed with important information available to you and your patients. There is a link on the directory page for your feedback.

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