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NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Recall of PC SPES and SPES Dietary Supplements

September 5, 2002 Update

The U.S. Food and Drug Administration (FDA) has warned consumers to stop taking the dietary supplements/herbal products PC SPES and SPES because they contain undeclared prescription drug ingredients that could cause serious health effects if not taken under medical supervision. In February 2002, BotanicLab, the California-based manufacturer of PC SPES and SPES, voluntarily recalled the products nationwide. Subsequently, on June 1, 2002, BotanicLab officially closed and ceased operations.

PC SPES is a capsule that is marketed for "prostate health," and SPES is a capsule marketed as an immune enhancer.

Advice to Consumers

Safety is a concern for users of these products. The FDA and the manufacturer have both advised consumers to discontinue the use of these products immediately.

NCCAM has funded four research studies of PC SPES to learn about its effectiveness, safety, and mechanisms of action in the body; only one involved research with patients. In June 2002, NCCAM placed all four studies on hold. Based on meetings since then with the scientists performing the major PC SPES studies, prostate cancer specialists, experts in herbal medicine, and representatives of Government and industry, NCCAM allowed the three laboratory studies of existing PC SPES supplies to resume to learn the cellular and molecular mechanisms of action of the herbs as opposed to the drug ingredients that contaminated the product.

Because of the promising data from the early studies of PC SPES and the public health importance of addressing advanced and hormone-refractory prostate cancer, NCCAM is interested in resuming studies of PC SPES with patients and funding new laboratory studies. However, NCCAM can only do so when a fully characterized and standardized, contaminant-free product using the original formulation becomes available.

NCCAM

To view the information from the FDA, please visit their Web site at www.fda.gov/medwatch/SAFETY/2002/safety02.htm#spes.

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