DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC

Dear Health Care Professional Colleague:

The Food and Drug Administration (FDA) needs your help. The agency is investigating whether the use of dietary supplements containing kava (also known as kava kava or *Piper methysticum*) is associated with liver toxicity. To help us determine whether there is a problem in the United States, we are asking that you review your cases of liver toxicity to determine if any may be related to the use of kava-containing dietary supplements.

Products containing herbal extracts of kava have been implicated in cases of serious liver toxicity in Germany and Switzerland. Approximately 25 reports of hepatic toxicity associated with the use of products containing kava extracts have been reported in these countries. Serious hepatic adverse effects include hepatitis, cirrhosis, and liver failure. At least one patient required a liver transplant. Based on their assessment of the adverse events reported to them, the regulatory authority in Switzerland has prohibited the sale of products containing the kava extract associated with the adverse effects. Last month, the German authorities issued a proposal to remove all kava extract-containing products from the market.

FDA is investigating whether the use of kava-containing dietary supplements in the United States poses similar public health concerns. The agency has received several reports of serious injury allegedly associated with the use of kava-containing dietary supplements, with at least one report of hepatic failure requiring liver transplantation in a previously healthy young female.

Dietary supplements containing kava are promoted for a variety of uses, including relaxation (e.g., to relieve stress, anxiety, and tension), insomnia, and postmenstrual syndrome (PMS). The products are marketed to all segments of the population, including children, women, men, and the elderly.

Due to the potentially serious nature of these concerns, we urge you to report any cases of hepatic toxicity that you think may be related to the use of kava-containing dietary supplements. Adverse events associated with the use of dietary supplements should be reported as soon as possible to FDA's MedWatch program by telephone (1-800-332-1088) or through the Internet (http://www.fda.gov/medwatch).

Thank you in advance for your cooperation in assisting the FDA in investigating this potentially serious public health issue. For additional information, contact Steven Gitterman, M.D., Ph.D. at (301) 436-2371.

Sincerely yours,

Christine Lewis Taylor, Ph.D.
Director
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and Dietary Supplements
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