



BACKGROUND

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Information on Kava Dietary Supplements

- The Food and Drug Administration (FDA) issued a kava consumer advisory on March 25, 2002 stating that “Kava-Containing Dietary Supplements May Be Associated With Severe Liver Injury.” FDA acknowledged that it has not established a causal relationship between kava supplements and liver injury. The Council for Responsible Nutrition (CRN) agrees that this is consistent with today’s science.
- FDA advised that people with liver disease or liver problems, or persons who are taking drug products that can affect the liver, should consult a physician before using kava-containing supplements.
- FDA advised that consumers who use a kava-containing dietary supplement and who experience signs of illness associated with liver disease should also consult their physician. Symptoms of serious liver disease include jaundice (yellowing of the skin or whites of the eyes) and brown urine. FDA also identified non-specific symptoms of liver disease which can include nausea, vomiting, light-colored stools, unusual tiredness, weakness, stomach or abdominal pain, and loss of appetite.
- CRN has been engaged in an on-going dialogue with FDA and believes that FDA’s consumer advisory was an appropriate cautionary way to inform consumers of this rare potential risk.
- Consistent with FDA’s advisory, CRN has recommended that its members adopt elements of a voluntary cautionary label for kava. The language is consistent with the FDA advisory. CRN anticipates its individual member companies will act swiftly to implement these recommendations.
- The proposed voluntary cautionary label elements are as follows:

Ask a health care professional before use if you have or have had liver problems, frequently use alcoholic beverages, or are taking any medication.

Stop use and see a doctor if you develop symptoms that may signal liver problems, including jaundice (yellowing of the skin or whites of the eyes) and brown urine. Other nonspecific symptoms can include nausea, vomiting, light-colored stools, unusual tiredness, weakness, stomach or abdominal pain, and loss of appetite.

Not for use by persons under 18 years of age, or by pregnant or breastfeeding women.

Not for use with alcoholic beverages.

Excessive use, or use with products that cause drowsiness, may impair your ability to operate a vehicle or heavy equipment.

- CRN pointed out that most of the adverse event reports (AERs) appear to have included a number of confounding factors, such as use of drugs known or suspected to cause liver injury, or alcoholic beverages.
- FDA had several options for addressing kava. It is important to note that based on the scientific evidence, FDA chose to issue a consumer advisory. FDA did not issue a product recall. FDA did not call for a product warning. FDA did not take other regulatory actions.
- Although millions of people have taken kava dietary supplements over a period of decades, to date, less than 100 AERs have been reported in the U.S. and Europe, and less than 50 of these cases (18 in the U.S.; 29 in Europe) appear to involve liver problems. Kava was recently assessed by a panel of independent scientific experts, convened by CRN, who reviewed the available clinical studies on the safety of 28 major botanical products. The panel's conclusion, which will appear in a soon-to-be-published CRN paper, was that kava is safe.
- FDA will continue to investigate the relationship, if any, between the use of dietary supplements containing kava and liver injury. The agency will continue to review the science to determine if a scientific rationale for the reported association between kava supplements and liver problems exists. CRN will continue to work cooperatively with FDA.
- The FDA consumer advisory (and a related letter to health care professionals) can be found at <http://www.cfsan.fda.gov/~dms/addskava.html>.

03/27/02