

a series of fact sheets written  
by experts in the field of liver  
disease

## *HCV & CAM: Dietary Substances and the Food and Drug Administration (FDA)*

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*The Food and Drug Administration (FDA) is the federal agency responsible for drug and food safety. Drugs undergo years of rigorous testing on animals and humans before the FDA allows them to be marketed. On the other hand, herbs and supplements are classified as dietary supplements. This means they are regulated by different standards, called the Dietary Supplement Health and Education Act of 1994 (DSHEA).*

Under this act, the manufacturer must ensure the safety of the dietary supplement. However, unlike a drug, supplement makers do not need to test their product or prove its safety prior to marketing. If the safety of a product comes into question, the FDA's powers are weak. Supplement manufacturers do not need FDA approval and do not need to register their product.

Manufacturers are prohibited from making disease claims about supplements, unless the product "qualifies to bear the claim." For example, a company that sells calcium supplements can say their product "may reduce the risk of osteoporosis."

Manufacturers are allowed to make general claims about supplements' "effects on a structure or function." A milk thistle manufacturer cannot claim that their product cures hepatitis C. It can state that milk thistle may provide liver support.

The FDA's involvement is primarily after marketing. The FDA may monitor product labeling, information, and safety. Adverse event reporting is voluntary. The FDA's ability to perform effectively is weak due to poor funding and understaffing.

In 1998, the National Center for Complementary and Alternative Medicine (NCCAM) became a new center of the National Institutes of Health (NIH). Responding to the need for more research about the safety and efficacy of herbs and supplements, NCCAM and the NIH Office of Dietary Supplements established the first Dietary Supplements Research Centers with an emphasis on botanicals.

### *What is a Dietary Supplement?*

A dietary supplement is:

- Used to supplement the diet and contains at least one of the following: amino acids or enzymes; herbs or other botanicals; vitamins or minerals; and various other ingredients such as psyllium, fish oils, mushrooms or glandular products
- Intended to be ingested (taken orally)
- Not used solely as a food source
- Labeled as a dietary supplement

For example, garlic is a spice or a food. When garlic is put into a capsule, it becomes a dietary supplement.

### *Myths about Dietary Supplements*

Here are some common misconceptions about dietary supplements:

- Supplements must be tested before they can be sold to the public.

***(False)***

- The FDA must approve supplements before they can be sold to the public.

***(False)***

- Manufacturers of supplements must have solid research to support and advertise safety claims.

**(False)**

- Supplement manufacturers are required to include warnings and other important safety information on their products' labels.

**(False)**

- Manufacturers must practice quality control methods on their supplements.

**(False)**

- Manufacturers must guarantee that their products are pure and free of contaminants.

**(False)**

- The amounts and concentrations of supplements are consistent and reliable.

**(False)**

- Adverse events occurring as possibly related to the use of a supplement must be reported to the FDA.

**(False)**

- If the word "natural" appears on a product's label, this means it is safe.

**(False)**

- Supplements' side effects are always mild.

**(False)**

- If a supplement is unsafe, it cannot be sold.

**(False)**

- A "recall" on a harmful product guarantees this supplement has been removed from the market.

**(False)**


## References

- Summary of the Dietary Supplement Health and Safety Act of 1994  
[vm.cfsan.fda.gov/~dms/dietsupp.html](http://vm.cfsan.fda.gov/~dms/dietsupp.html)
- National Institutes of Health Office of Dietary Supplements Health Information  
[http://ods.od.nih.gov/Health\\_Information/Health\\_Information.aspx](http://ods.od.nih.gov/Health_Information/Health_Information.aspx)

## Other Factsheets in the Series: "Hepatitis C and Complementary and Alternative Medicine (CAM)"

- Overview
- Complementary and Alternative Medicine Resources
- HCV & CAM: Dietary Supplements to Avoid
- Dietary Substances and the Food and Drug Administration (FDA)
- Herbal Dietary Supplements Glossary
- Herbs and Dietary Supplements: Making Safer and Wiser Choices
- Herbs and Hepatitis C
- Information and Finding a Practitioner
- Internet Resources for Dietary Supplements
- Self-Help Acupressure for Hepatitis C

**For more information about hepatitis C, hepatitis B and HCV coinfections, please visit [www.hcvadvocate.org](http://www.hcvadvocate.org).**

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<p><b>Executive Director</b> <b>Editor-in-Chief, HCSP Publications</b> Alan Franciscus</p> <p><b>Design</b> Paula Fener</p> <p><b>Production</b> C.D. Mazoff, PhD</p> <p><b>Contact information:</b> Hepatitis C Support Project PO Box 427037 San Francisco, CA 94142-7037 <a href="mailto:alanfranciscus@hcvadvocate.org">alanfranciscus@hcvadvocate.org</a></p>	<p>The information in this fact sheet is designed to help you understand and manage HCV and is not intended as medical advice. All persons with HCV should consult a medical practitioner for diagnosis and treatment of HCV.</p> <p>This information is provided by the Hepatitis C Support Project • a nonprofit organization for HCV education, support and advocacy • © 2007 Hepatitis C Support Project • Reprint permission is granted and encouraged with credit to the Hepatitis C Support Project.</p>
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