

# FDA News

FOR IMMEDIATE RELEASE  
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## **FDA Warns Consumers to Stop Using Hydroxycut Products *Dietary Supplements Linked to One Death; Pose Risk of Liver Injury***

The U.S. Food and Drug Administration is warning consumers to immediately stop using Hydroxycut products by Iovate Health Sciences Inc., of Oakville, Ontario and distributed by Iovate Health Sciences USA Inc. of Blasdell, N.Y. Some Hydroxycut products are associated with a number of serious liver injuries. Iovate has agreed to recall Hydroxycut products from the market.

The FDA has received 23 reports of serious health problems ranging from jaundice and elevated liver enzymes, an indicator of potential liver injury, to liver damage requiring liver transplant. One death due to liver failure has been reported to the FDA. Other health problems reported include seizures; cardiovascular disorders; and rhabdomyolysis, a type of muscle damage that can lead to other serious health problems such as kidney failure.

Liver injury, although rare, was reported by patients at the doses of Hydroxycut recommended on the bottle. Symptoms of liver injury include jaundice (yellowing of the skin or whites of the eyes) and brown urine. Other symptoms include nausea, vomiting, light-colored stools, excessive fatigue, weakness, stomach or abdominal pain, itching, and loss of appetite.

"The FDA urges consumers to discontinue use of Hydroxycut products in order to avoid any undue risk. Adverse events are rare, but exist. Consumers should consult a physician or other health care professional if they are experiencing symptoms possibly associated with these products," said Linda Katz, M.D., interim chief medical officer of the FDA's Center for Food Safety and Applied Nutrition.

Hydroxycut products are dietary supplements that are marketed for weight-loss, as fat burners, as energy-enhancers, as low carb diet aids, and for water loss under the Iovate and MuscleTech brand names. The list of products being recalled by Iovate currently includes:

- Hydroxycut Regular Rapid Release Caplets
- Hydroxycut Caffeine-Free Rapid Release Caplets
- Hydroxycut Hardcore Liquid Caplets
- Hydroxycut Max Liquid Caplets
- Hydroxycut Regular Drink Packets
- Hydroxycut Caffeine-Free Drink Packets
- Hydroxycut Hardcore Drink Packets (Ignition Stix)
- Hydroxycut Max Drink Packets
- Hydroxycut Liquid Shots
- Hydroxycut Hardcore RTDs (Ready-to-Drink)
- Hydroxycut Max Aqua Shed
- Hydroxycut 24
- Hydroxycut Carb Control
- Hydroxycut Natural

Although the FDA has not received reports of serious liver-related adverse reactions for all Hydroxycut products, Iovate has agreed to recall all the products listed above. Hydroxycut Cleanse and Hoodia products are not affected by the recall. Consumers who have any of the products involved in the recall are advised to stop using them and to return them to the place of purchase. The agency has not yet determined which ingredients, dosages, or other health-related factors may be associated with risks related to these Hydroxycut products. The products contain a variety of ingredients and herbal extracts.

Health care professionals and consumers are encouraged to report serious adverse events (side effects) or product quality problems with the use of these products to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, fax or phone.

–Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)

–Regular Mail: Use FDA postage paid form 3500 found at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

–Fax: 800-FDA-0178

–Phone: 800-FDA-1088

The FDA continues to investigate the potential relationship between Hydroxycut dietary supplements and liver injury or other potentially serious side effects.

**For more information:**

[Hydroxycut Products](#)

[Dietary Supplements -- Overview](#)

[FDA 101: Dietary Supplements](#)

[NIH Office of Dietary Supplements](#)