

Subject: ALFOODACT 117-2009 Recalls Hydroxycut Products Due to Possible Liver Injuries

Date Issued: May 1, 2009

1. REFERENCES:

- a. DLAR 4155.26/AR 40-660/NAVSUPINST 10110.8c/AFI 48-116/MCO 10110.38c, DOD Hazardous Food & Nonprescription Drug Recall System.
- b. Allied Communications Publication 121, US SUPP-1 (f).
- c. AskKaren: <http://www.fsis.usda.gov/food%5Fsafety%5Feducation/ask%5Fkaren/#Question>
- d. FDA Posting: <http://www.fda.gov/consumer/updates/hydroxycut050109.html>

2. BACKGROUND:

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

3. PRODUCTION DATES/IDENTIFYING CODES:

View graphics of some of the product being recalled:
<http://www.fda.gov/consumer/updates/hydroxycut050109.pdf>

The list of products being recalled by lovate currently includes all dates, lots, and sizes of the following:

- 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 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.

4. Manufacturer/Distributor

Iovate Health Sciences USA Inc.
Blasdell, N.Y.

5. DISTRIBUTION: Nationwide

6. REASON FOR ACTION: Liver Injuries

7. INSTRUCTIONS AND ADDITIONAL INFORMATION FOR MESSAGE RECIPIENTS:

a. Immediately inventory stocks to identify the above items and secure in a "Medical Hold" status to provide assurance of no further issue/sale/use. POSITIVE FINDINGS should be reported to Accountable Officers/Vendor Representatives of that facility. Accountable Officer/Agency representatives/Buyers/Contracting Officers should seek refund/credit/replacement through the normal distribution channel with which the product was received (i.e. Distribution Centers, Prime Vendors, Manufacturers).

b. Ships at sea are authorized to destroy or dispose of recalled products at their discretion. Documentation for the number of pounds and cases, and any additional pertinent information must be signed by the Accountable Officer and is required for the purpose of recouping to the government the cost of the product involved. In order to get credit please use a SF 364 and forward to your supporting FISC and copy furnished to NAVSUP 51. Your supporting FISC should forward to the account manager at DSCP. The form should include the number of the recall authorizing the survey action. Home ported ships/gallies will utilize DD form 1149 to transfer w/ reimbursement to the PV. The PV will submit credit invoice to the account manager at DSCP.

c. Except for Prime Vendors, POSITIVE and NEGATIVE RESPONSES directly to DSCP Consumer Safety Officer (CSO) are NOT required. Prime Vendors should report finding to their assigned Contracting Officer and courtesy copy the Consumer Safety Officer (dscpconssafofc@dla.mil). Other agencies such as DeCA, AAFES, MWR, VA, MCCA, etc. should report POSITIVE and NEGATIVE responses to their agencies recall coordinator.

d. When corresponding with DSCP concerning this message please include this message's subject in your subject line.

8. The Point of Contact for this ALFOODACT message is CW4 Ramona Hemphill, Consumer Safety Officer, at DSCP-FTW. VOICE, DSN: 444-2922, Commercial (215) 737-2922, or by FAX, DSN: 444-7526, or Commercial, (215) 737-7526.

Any individual or office that would like to receive recall messages electronically can forward their email address to dscpconssafofc@dla.mil

Previous recalls and frequently asked questions are available at the following web site:
<https://www.dscp.dla.mil/subs/fso/alfood/alfood.asp>

The navigation tool to the left allows you to view DSCP Alerts and Archived Vendor Recalls also.

Very Respectfully,
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