

SUBJECT: ALFOODACT 118-2009 Additional Information to ALFOODACT 117-2009 Iovate Recalls HydroxyCut Products Due to Possible Liver Injuries

Date Issued: May 4, 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/oc/po/firmrecalls/iovate05_09.html

2. BACKGROUND :

Iovate Health Sciences USA, Inc. of Blasdell, New York and Ontario, Canada announced today that it is voluntarily recalling Hydroxycut branded products sold in the United States.

Iovate initiated a voluntary recall when it became aware that the U.S. Food and Drug Administration's assessment of 23 reports about consumers having experienced liver-related problems, as well as a small number of published case reports, was different from Iovate's analysis. On May 1, 2009, the FDA issued an advisory which states that, "Although the liver damage appears to be relatively rare, FDA believes consumers should not be exposed to unnecessary risk." The number of adverse event reports described by the FDA is small relative to the many millions of people who have used Hydroxycut products over the 7 years referenced by the FDA. Iovate's own assessment of the potential risk associated with the use of these products differs from that expressed by the Agency.

Every product marketed by Iovate is evaluated during its development for the safety of its individual ingredients. Additionally, independent thirdparty experts from the leading independent scientific firm specializing in ingredient assessment, toxicology and product safety for the nutritional and pharmaceutical industry review the safety of Iovate's ingredients and formulas before products are introduced in the marketplace. Only after this external review is completed does Iovate release a formula.

However, out of an abundance of caution and because consumer safety is Iovate's top priority, Iovate is voluntarily recalling these Hydroxycut-branded products.

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 Iovate currently includes all dates, lots, and sizes of the following:

HYDROXYCUT RAPID RELEASE REGULAR CAPLETS

631656893649 Hydroxycut 140ct Cap US

631656833621 Hydroxycut 60 GNC US

631656600988 Hydroxycut 300ct Caplets US
631656890129 Hydroxycut 36ct Cap US "with CARDS"
631656282245 Hydroxycut 160ct Cap US *Discontinued*
631656873214 Hydroxycut 58ct Cap US
631656813418 Hydroxycut 70ct Cap US
631656808612 Hydroxycut 70ct Caps US *Discontinued*
631656808117 Hydroxycut 100 cap US *Discontinued*
631656818642 Hydroxycut 140ct Cap US *Discontinued*
631656882414 Hydroxycut 80ct Caps US *Discontinued*
631656843262 Hydroxycut 210ct Cap US
631656828665 Hydroxycut 210 cap US *Discontinued*
631656600582 Hydroxycut 60ct + 1 Hydroxycut Sachet WB US
631656600476 Hydroxycut 72ct + Hydroxycut Sachet WB US
631656600483 Hydroxycut 100ct Caplets US
631656600506 Hydroxycut 150ct Caplets US
631656601251 Hydroxycut 170 Caplets US
631656600452 Hydroxycut 30ct Caplets US

HYDROXYCUT HARDCORE LIQUID CAPSULES

631656600650 Hydroxycut Hardcore 120ct US
631656600834 Hydroxycut Hardcore 210ct US
631656001778 Hydroxycut Hardcore 30ct US
631656601435 Hydroxycut Hardcore 252ct US
631656601848 Hydroxycut Hardcore 30ct US Trial - Bodybuilding.com
631656601749 Hydroxycut Hardcore 120ct US NEW
631656601763 Hydroxycut Hardcore 252ct US
631656601756 Hydroxycut Hardcore 210ct US NEW

HYDROXYCUT CAFFEINE-FREE CAPLETS

631656801224 Hydroxycut Caffeine Free 140ct Cap US
631656821246 Hydroxycut Caffeine Free 330ct Cap US
631656801217 Hydroxycut Caffeine Free 100ct Cap US
631656801231 Hydroxycut Caffeine Free 58ct Cap US
631656899122 Hydroxycut Caffeine Free 36ct Cap US
631656600544 Hydroxycut Caffeine Free 60ct US
631656600551 Hydroxycut Caffeine Free 72ct US
631656600568 Hydroxycut Caffeine Free 100ct US

HYDROXYCUT MAX CAPLETS

631656601466 Hydroxycut Max 120ct bonus + 1Hyd Max Sachet WB US
631656601633 Hydroxycut Max 210ct Bonus + 1 Hyd Max Sachet WB US

HYDROXYCUT REGULAR DRINK PACKET

631656860191 Hydroxycut Weight Loss Drink Mix 21pk Sachet - Wild Berry US
631656860313 Hydroxycut Weight Loss Drink Mix 21pk Sachet - Country Lemonade US

HYDROXYCUT HARDCORE DRINK PACKET (IGNITION STIX)

631656701326 Hydroxycut Hardcore Drink Mix 2.7g Sachet - Blue Raspberry US
631656701319 Hydroxycut Hardcore Drink Mix 2.6g Sachet - Fruit Punch US
631656760118 Hydroxycut Hardcore Drink Mix 40pk x 2g Sachet - Fruit Punch US
631656760125 Hydroxycut Hardcore Drink Mix 40pk x 2g Sachet - Blue Raspberry US

HYDROXYCUT CAFFEINE-FREE DRINK PACKET

631656760095 Hydroxycut Caffeine Free Drink Mix 21pk x 3.6g Sachet - Raspberry Ice US

HYDROXYCUT MAX DRINK PACKET

631656860375 Hydroxycut Max Drink Mix 40pk x 2.4g Sachet - Wild Berry US

631656860382 Hydroxycut Max Drink Mix 40pk x 2.7g Sachet - Lemonade US

HYDROXYCUT LIQUID SHOT

631656800159 Hydroxycut Weight Loss Single Shot 2oz - Wild Berry US

631656860207 Hydroxycut Weight Loss Shot 2 x 2oz Pk - Wild Berry US

631656860498 Hydroxycut Instant Weight Loss Shot 12 x 2oz - Wild berry US

HYDROXYCUT MAX AQUA SHED

631656601855 Hydroxycut Max Aqua Shed 60ct Capsules US

HYDROXYCUT HARDCORE RTD

631656860436 Hydroxycut Hardcore 4 x8oz RTD - Grape Infusion US

631656860399 Hydroxycut Hardcore 4 x 8oz RTD - Triple WildBerry US

631656860665 Hydroxycut Hardcore 12-pack RTD - Grape Infusion US

631656860467 Hydroxycut Hardcore 3 x 4-pack RTD - Grape Infusion US

631656860443 Hydroxycut Hardcore 3 x 4-pack RTD - Triple Wildberry US

631656860443 Hydroxycut Hardcore 3 x 4-pack RTD - Triple Wildberry US

631656860568 Hydroxycut Hardcore 12-pack RTD - Triple Wildberry US

HYDROXYCUT 24

631656600933 Hydroxycut 24 (96 caps/ blister pack) US

HYDROXYCUT CARB CONTROL

631656800036 Hydroxycut Carb Control 58ct Cap US

631656800029 Hydroxycut Carb Control 100ct Cap US

631656800012 Hydroxycut Carb Control 140ct Cap US

HYDROXYCUT NATURAL

631656600889 Hydroxycut Natural 100ct US

Please note that Hydroxycut Hoodia and Hydroxycut Cleanse products are not included in this recall; nor are any other Iovate products.

4. Manufacturer/Establishment Number:

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,

Mrs. Ramona Hemphill
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