Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: November 13, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: USPlabs LLC Recall [Food]

AFFECTED PRODUCT: **OxyElite Pro Dietary Supplements Due to Possible Health Risk. See List of UPC Codes Below**

SUMMARY: **Unclassified Recall; USPlabs LLC, Dallas, TX is voluntarily conducting a national recall of all lots and sizes of the OxyElite Pro dietary supplement products listed below. These products contain Aegeline, a synthesized version of a natural extract from the Bael tree. Epidemiological evidence shows that use of these products has been associated with serious adverse health consequences, namely serious liver damage or acute liver failure, concentrated in Hawaii. Product was distributed nationwide through retail stores, mail orders and direct delivery. Recommend notification of affected stores via phone, fax or e-mail; Information is provided in case of a consumer inquiry.**

SUGGESTED ACTION: **Consumers can contact USPlabs at 1(800) 890-3067 (Monday-Friday, 9 am - 5 pm EST) or info@usplabsdirect.com. Adverse reactions may be reported to the FDA MedWatch Adverse Event Reporting program online at http://www.fda.gov/medwatch/getforms.htm[1], by regular mail, or by FDA's MedWatch Hotline 1-800-FDA-1088. Furthermore, if any recalled products are found, please notify this office at 317-233-3213.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company

USPlabs LLC Announces a Recall of OxyElite Pro Dietary Supplements Due to Possible Health Risk

Contact:
Consumer:
USPlabs LLC
1-800-890-3067

FOR IMMEDIATE RELEASE —November 9, 2013 – USPlabs LLC, Dallas, TX is voluntarily conducting a national recall of all lots and sizes of the OxyElite Pro dietary supplement products listed below. These products contain Aegeline, a synthesized version of a natural extract from the Bael tree.

Epidemiological evidence shows that use of these products has been associated with serious adverse health consequences, namely serious liver damage or acute liver failure, concentrated in Hawaii. Investigations are ongoing into a potential causal relationship. The Company agrees with FDA that a national recall is appropriate as a precautionary measure. Product was distributed nationwide through retail stores, mail orders and direct delivery.

OxyElite Pro Super Thermo capsules
2 count capsules UPC #094922417275
10 count capsules UPC #094922417251
10 count capsules UPC #094922417268
21 count capsules UPC #094922426604
90 count capsules UPC #094922395573
90 count capsules "Pink label" UPC #094922447906
180 count capsules UPC #094922447852

OxyElite Pro Ultra-Intense Thermo capsules
3 count capsules UPC #094922447883
3 count capsules UPC #094922447876
90 count capsules UPC #094922395627
180 count capsules UPC #094922447869

OxyElite Pro Super Thermo Powder
Fruit Punch 0.15 oz UPC #094922417237
Fruit Punch 0.15 oz UPC #094922447517
Fruit Punch 4.6 oz UPC #094922426369
Fruit Punch 5 oz. UPC #094922447487
Blue Raspberry 4.6 oz UPC #094922426376
Grape Bubblegum 4.6 oz UPC #094922447500
Green Apple 4.6 oz. UPC #094922426499

No other products produced by USPlabs are subject to recall. Consumers who have purchased the products should immediately discontinue use of the product and return it to where they purchased it for a refund. Contact your health care professional if you have experienced any adverse effects.

Consumers can contact USPlabs at 1(800) 890-3067 (Monday-Friday, 9 am - 5 pm EST) or info@usplabsdirect.com. Adverse reactions may be reported to the FDA MedWatch Adverse Event Reporting program online at http://www.fda.gov/medwatch/getforms.htm[1], by regular mail, or by FDA's MedWatch Hotline 1-800-FDA-1088.

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RSS Feed for FDA Recalls Information[2] [what's this?[3]]

Recalled Product Photos Are Also Available on FDA's Flickr Photostream.[4]