Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: December 2, 2013

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

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

SUBJECT: IQ Formulations [Drug]

AFFECTED PRODUCT: **Hydravax 45 Capsule bottles (Lot # 2458, Exp # 07/16) dietary supplement.**

SUMMARY: **Unclassified Recall; IQ Formulations, of Sunrise, Florida is initiating a precautionary and proactive recall of all lots of its 45-capsule bottles of HYDRAVAX due to potential inclusion of an unlisted ingredient. The FDA has advised IQ Formulations that an analysis of a sample from one lot of HYDRAVAX (Lot # 2458, Exp # 07/16) revealed the presence of an undeclared ingredient – a diuretic. Diuretics are prescription drugs and thus, are not listed on the packaging label for HYDRAVAX. Consumers are hereby notified not to use the product.**

The recalled HYDRAVAX was distributed nationwide in retail stores and mail order.

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax, or e-mail. All consumers who have purchased HYDRAVAX 45 capsule bottles are urged to return them to the place of purchase for a full refund. Consumers and distributors with questions regarding this recall should contact IQ Formulations Customer Service at Recall@iqformulations.com or by phone at 800-626-1022 from Monday through Friday from 9 am to 5 pm EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Furthermore, if any recalled products are found, notify this office at 317-233-8475.**

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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.

IQ Formulations Issues a Voluntary Recall of HYDRAVAX Dietary Supplement Due to Possible Undeclared Ingredient

Contact:
Consumer:
(800) 626-1022
Email: Recall@iqformulations.com

FOR IMMEDIATE RELEASE - November 29, 2013 - IQ Formulations, of Sunrise, Florida is initiating a precautionary and proactive recall of all lots of its 45-capsule bottles of HYDRAVAX due to potential inclusion of an unlisted ingredient. The FDA has advised IQ Formulations that an analysis of a sample from one lot of HYDRAVAX (Lot # 2458, Exp # 07/16) revealed the presence of an undeclared ingredient – a diuretic. Diuretics are prescription drugs and thus, are not listed on the packaging label for HYDRAVAX. Consumers are hereby notified not to use the product.

Possible effects of using a diuretic include an electrolyte imbalance due to water loss. Symptoms include: polyuria, nausea, vomiting, weakness, lassitude, fever, flushed face, and hyperactive deep tendon reflexes. Fluid and electrolyte imbalances are the most important concern. Excessive doses of diuretics may elicit hyperkalemia, dehydration, nausea, vomiting and weakness and possibly hypotension. Overdosing with a diuretic has been associated with hypokalemia, hypochloremia, hyponatremia, dehydration, lethargy and gastrointestinal irritation. People experiencing these problems should seek immediate medical attention.

No illnesses or consumer complaints have been reported to date in connection with this issue. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

The product comes in a 45 capsule bottle. The recalled HYDRAVAX was distributed nationwide in retail stores and mail order.

Production of the product has been suspended while the company continues their investigation as to the source of the potential unlisted ingredient. IQ Formulations receives this product from the manufacturer in sealed packages and with a certificate of analysis that represents that the product contains only the lawful and legitimate listed ingredients.

All consumers who have purchased HYDRAVAX 45 capsule bottles are urged to return them to the place of purchase for a full refund. Consumers and distributors with questions regarding this recall should contact IQ Formulations Customer Service at Recall@iqformulations.com or by phone at 800-626-1022 from Monday through Friday from 9 am to 5 pm EST. This recall action is being conducted with the knowledge of the FDA.

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Photo: Product Labels

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

Page Last Updated: 11/29/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.