Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: November 30, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Glades Drugs - RECALL [Drug]

AFFECTED PRODUCT: **Compounded multivitamin capsules containing high amounts of Vitamin D3 (Cholecalciferol)**

SUMMARY: **Unclassified Recall; Consumption of this product may result in vitamin D toxicity, which may be severe and may lead to life-threatening outcomes if left untreated.**

The recalled products were distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. Health care providers should quarantine and return any products subject to this recall to the company at: Glades Drugs, 109 S. Lake Ave., Pahokee, FL 33476. Glades Drugs sent recall letters to patients, attempted to contact them by phone, and called prescribing physicians.**

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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.

FDA Announces Glades Drugs' Nationwide Voluntary Recall Of Compounded Multivitamins Containing High Amounts Of Vitamin D3 (Cholecalciferol)

FDA Press Release

For Immediate Release

November 25, 2015

Contact

Consumers

Faith Washington, Pharmacist
(866) 597-3296
Firm Press Release

The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of compounded multivitamin capsules containing high amounts of Vitamin D3 (Cholecalciferol), distributed nationwide by Glades Drugs in Pahokee, Florida. FDA has received reports of several adverse events potentially associated with these compounded capsules made by Glades Drugs.

Consumption of this product may result in vitamin D toxicity, which may be severe and may lead to life-threatening outcomes if left untreated. Patients suffering adverse effects from high Vitamin D levels (Cholecalciferol) may not initially show symptoms. Therefore, patients who have received these compounded capsules should stop taking this medication and immediately seek medical attention.

Symptoms of short-term vitamin D toxicity are due to high calcium levels (also known as hypercalcemia) and include confusion, increased urination, increased thirst, loss of appetite, vomiting, and muscle weakness. Acute hypercalcemia may intensify tendencies for heart arrhythmias and seizures and may increase the effects of certain heart drugs. Long-term toxicity may cause kidney failure, increase in calcium deposits in the blood and soft tissue, bone demineralization and pain. Patients with conditions such as liver disease or chronic kidney failure may be at increased risk for developing vitamin D toxicity.

Health care providers should quarantine and return any products subject to this recall to the company at: Glades Drugs, 109 S. Lake Ave., Pahokee, FL 33476. Glades Drugs sent recall letters to patients, attempted to contact them by phone, and called prescribing physicians.

FDA encourages health care professionals and patients to report adverse reactions to the FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

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