From:	Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Cc:	Pharmacy_Subscriberlist@DCA
Subject:	Compounded Multivitamins by Glades Drugs: Recall - High Amounts of Vitamin D3 (Cholecalciferol)
Date:	Monday, November 30, 2015 10:37:25 AM

AUDIENCE: Pharmacy, Health Professional, Patient

ISSUE: The U.S. Food and Drug Administration is alerting health care professionals and patients of a 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.

BACKGROUND: 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.

RECOMMENDATION: 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[11/25/2015 - Recall Notice - FDA]