From:	General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Subject:	Recall - Apexxx by Nuway Distributors - Undeclared Drug Ingredient
Date:	Thursday, December 24, 2015 9:45:13 AM

AUDIENCE: Consumer

ISSUE: Nuway Distributors LLC is voluntarily recalling all lots of Apexxx tablets to the consumer level. FDA analysis found Apexxx to contain amounts of the PDE-5 Inhibitor, sildenafil, which is the active ingredient in an FDA-approved drug for erectile dysfunction (ED) making this a tainted dietary supplement and unapproved drug. Sildenafil is not listed on the product labels. Sildenafil may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels that may be life-threatening. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, the product may cause side effects, such as headaches and flushing.

BACKGROUND: This product marketed as a dietary supplement for male sexual enhancement. Apexxx is packaged in a single blister pack containing 1 tablet. UPC 705105963617. All lots of Apexxx are included in this recall sold in 2014 to June 2015. Apexxx can be identified by the black packaging, it is a yellow diamond shaped tablet embossed with the wording "APEXXX" on it. Apexxx was sold in retail store located in Orlando, Florida for further sale in smoke shops, convenient stores and gas stations. Apexxx may also have been further sold online.
In an abundance of caution, Nuway Distributors LLC is also removing all lots of Opal tablets to the consumer level because this product is sourced from the same vendors as the Apexxx product. Opal is packaged in a single blister pack containing 1 tablet, UPC 794504852400. Opal can be identified by the black packaging, it is a black diamond-shaped tablet. Opal was also sold in a retail store located in Orlando, Florida for further sale in smoke shops, convenience stores and gas stations. Opal may also have been further sold online.

RECOMMENDATION: Consumers and retailers that have Apexxx or Opal should stop using and distributing this product immediately and arrange return of the products. Consumers with questions regarding this voluntary recall can contact Nuway Distributors LLC by email at nuwaydistributors@gmail.com and calling at 407-722-0061. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.

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.

Read the MedWatch Safety Alert, including a link to the Firm Press Release, at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm478953.htm

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