Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: December 28, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Nuway Distributors LLC - RECALL [Drug]

AFFECTED PRODUCT: **APEXXX and OPAL tablets**

SUMMARY: **Unclassified Recall; The recall is due to FDA analysis that has 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 tainted dietary supplement and unapproved drug. OPAL is also being recalled because this product is sourced from the same vendors as the APEXXX product**

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 embosses with the wording "APEXXX" on it.

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 [note any embossing].

APEXXX and OPAL were sold in a retail store located in Orlando, Florida for further sale in smoke shops, convenient stores and gas stations. APEXXX and OPAL may also have been further sold online.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this voluntary recall can contact Nuway Distributors llc by email at nuwaydistributors@gmail.com and calling at 407-722-0061.**

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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.

Nuway Distributors llc Issues Voluntary [Worldwide/Nationwide] Recall of APEXXX Due to Presence of Undeclared Sildenafil

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.

For Immediate Release

December 23, 2015

Contact

Consumers

Nuway Distributors llc
nuwaydistributors@gmail.com
407-722-0061

Firm Press Release

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 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.

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 embosses 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 [note any embossing]. 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.

Nuway Distributors llc is now notifying its customers by press release and is arranging for a return of all recalled and removed products.

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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular Mail or FAX: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request reporting form, then complete and return to the address on the pre-addresses form, or submit by fax to 1-800-FDA-0178.

This recall and market action are being conducted with the knowledge of the U.S. Food and Drug Administration.

"As Nuway Distributors llc receives this product from overseas in a sealed package, representing that it contains only lawful and legitimate ingredients, we are relying on the representations of the Food and Drug Administration

that the public interest would best be served by voluntarily complying with their request to get the product off the shelves. Our goal is to protect the safety of the consumer," stated Nuway Distributors llc.

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