



Mitchell E. Daniels, Jr.  
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.  
State Health Commissioner

**DATE:** December 6, 2010

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

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

**SUBJECT:** Intelli Health Products Expanded Recall

**SUGGESTED**

**ACTION:** **Unclassified Recall; Duro Extend Capsules For Men due to product found to be adulterated with Sulfoaidenafil, an analogue of Sildenafil which is an FDA approved drug used in the treatment of Erectile Dysfunction (ED), to include all lot codes; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled may be distributed in the State of Indiana. Duro Extend Capsules are sold nationwide. The products are sold individually as a blister pack containing one capsule per unit, in 12-pack or 24-pack display boxes, and in bulk in 3 count and 10 count bottles. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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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.**

**Intelli Health Products, Issues an Expansion to All Lots of their Voluntary Nationwide Recall of Duro Extend Capsules for Men Marketed as Dietary Supplements**

**Contact:**

Intelli Health Products  
Intellihealth1@gmail.com

**FOR IMMEDIATE RELEASE** - December 2, 2010 - Intelli Health Products announced today that it is expanding their voluntary nationwide recall of Duro Extend Capsules For Men, to include all lot codes. Intelli Health Products is conducting this recall after being informed by representatives of the Food and Drug Administration (FDA) that laboratory analysis of Duro Extend Capsules For Men found the product to be adulterated with Sulfoaidenafil, an analogue of Sildenafil which is an FDA approved drug used in the treatment of Erectile Dysfunction (ED), making it an unapproved new drug.

Use of this product may pose a threat to consumers because the analogue may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. ED is a common problem in men with these conditions, and consumers may seek these types of products to enhance sexual performance.

Duro Extend Capsules are sold nationwide. The products are sold individually as a blister pack containing one capsule per unit, in 12-pack or 24-pack display boxes, and in bulk in 3 count and 10 count bottles. Lot number and expiration dates appear on the seal. Consumers who have Duro Extend Capsules in their possession should stop using them immediately.

In the event of any adverse side effects due to the consumption of these products, consumers should contact a physician immediately. Any 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.

Online: <http://www.fda.gov/MedWatch/report.htm><sup>9</sup>

Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm><sup>10</sup>. Mail to address on the pre-addressed form.

Fax: 1-800-FDA-0178

The Company is advising consumers to return any unused Duro Extend Capsules, to the retail location from which it was purchased or to the Company directly if it was purchased from the Company as a part of its Direct Response Program. Consumers can send unused capsules directly to the company.

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Intelli Health Products conducts stringent quality control testing on both raw materials and finished products. Previous testing protocols did not include a test for the presence of Sulfoaidenafil but Intelli Health Products assures consumers that this deficiency is being rectified. Intelli Health Products apologizes for any inconvenience and expresses its concern for the health of consumers by conducting a voluntary recall action. Intelli Health Products promises to ensure quality and integrity of all its products and the company is working closely with the FDA in the recall process.