



DATE: November 4, 2010

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

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

SUBJECT: Intelli Health Products Recall

SUGGESTED

ACTION: **Unclassified Recall; Duro Extend Capsules For Men adulterated with Sulfoaidenafil, an analogue of sildenafil which is an FDA approved drug used in the treatment of Erectile Dysfunction(ED); 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 as a blister pack containing one capsule per unit of use 24-packs in a Box. Lot number and expiration date appears on the seal. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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 a Voluntary Nationwide Recall of Duro Extend Capsules for Men Marketed as Dietary Supplements

Company Contact:

Intelli Health Products
80 Southwest 8th Street
Miami, FL 33130
Phone: 1-800-861-6022
Email : Intellihealth1@gmail.com

FOR IMMEDIATE RELEASE – Miami, FL - October 27, 2010 – Intelli Health Products, announced today that it is conducting a voluntary nationwide recall of Duro Extend Capsules For Men. 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 sample 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 as a blister pack containing one capsule per unit of use 24-packs in a Box. Lot number and expiration date appears on the seal.

Lot Number	Expiration Date
80320A	3/2011
80516A	5/2011
80710A	6/2011
80819	8/2011
80519A	8/2011
81104	11/2011
81104A	11/2011
81104B	11/2011
90226A	2/2012
90226	2/2012
90226B	2/2012
90612	6/2012

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 events that may be related to the use of these products should be reported to the FDA's Med Watch Program by fax at 1-800-FDA-0178 or by mail at Med Watch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787. or on the Med watch website at <http://www.fda.gov/safety/medwatch/default.htm>⁹

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.

Intelli Health Products

80 Southwest 8th Street

Miami, FL 33130

Phone: 1-800-861-6022

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.

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Photos: Product Labels¹⁰