Indiana State Department of Health
An Equal Opportunity Employer

Mitchell E. Daniels, Jr.
Governor

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

DATE: April 6, 2010

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

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

SUBJECT: Kanec USA Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; Recall of Stud Capsule For Men; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. Stud Capsule For Men 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 product is 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.

Kanec USA Inc., Issues a Voluntary Nationwide Recall of Stud Capsule For Men Marketed as Dietary Supplements

Contact:
KANEC USA INC.,
kanecusainc@bellsouth.net

FOR IMMEDIATE RELEASE -- Davie, FL – April 2, 2010- KANEC USA INC, 5061, South State Road 7. Ste 602, Davie FL 33314, announced today that it is conducting a voluntary nationwide recall of Stud Capsule For Men Lot #060607-01/060108-01 Exp 6-2013. Kanec USA Inc, is conducting this recall after being informed by representatives of the the Food and Drug Administration (FDA) that laboratory analysis of Stud Capsule Lot 060607-01/060108-01 Exp 6-2013 sample found the product to be adulterated with Sildenafil, 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.

Stud Capsule For Men 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.

Consumers who have Stud Capsule For Men Lot 060607-01/060108-01 Exp 6-2010 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[1]

The Company is advising consumers to return any unused Stud Capsule For Men, 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 capsule to directly to the company.

KANEC USA INC
5061 SOUTH STATE ROAD 7, U602
DAVIE FL 33314
Phone: 954-583-5840
Fax: 954-583-5885

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

#