JANSSEN PHARMACEUTICA PRODUCTS, L.P.

URGENT CLASS 1 DRUG RECALL NOTIFICATION PATIENT LEVEL

Subject: DURAGESIC®(fentanyl transdermal system) CII 75 mcg/h NDC #50458-035-05 Lot Control Number 0327192 (expiration October 2005).

February 17, 2004

Janssen Pharmaceutica Products, LP would like to inform you of a Class I Recall to users for DURAGESIC®(fentanyl transdermal system) 75 mcg/h, NDC #50458-035-05, Control Number 0327192 (expiration October 2005).

A potential seal breach on one edge may allow drug to leak from the patch.

Exposure to the Duragesic hydrogel contents could result in an increased absorption of the opioid component, fentanyl, leading to increased drug effect, including nausea, sedation, drowsiness, or potentially life threatening complications.

Conversely, if the hydrogel contents leak out of the patch, there may not be adequate medication to treat the patients' pain. In an opioid tolerant patient, this may lead to withdrawal symptoms, which include sweating, sleeplessness and abdominal discomfort.

Anyone who comes in contact with the leaked medication is advised to rinse exposed skin thoroughly with water only. *Do not use soap.*

It is estimated that fewer than 19,000, or less than 5 percent of the 440,000 patches from this single manufacturing lot may leak.

Only Control Number 0327192 is subject to this recall. All other control numbers are unaffected by the recall.

This corrective action and return policy are being made with the knowledge of the FDA (Food and Drug Administration) and the DEA (Drug Enforcement Administration.)

Please check your stock immediately. If you have any product with Control Number 0327192, please **stop** the distribution of the lot immediately, fill out the included Business Reply Card indicating quantities to be returned, and promptly mail to: Universal Rx Solutions,** 2084-900 M, Lake Industrial Court, PO Box 998-30012, Conyers, GA 30013-5758 or fax your response to 1-770-785-9161. Once received, Universal Rx Solutions will send a 222 form, instructions and a mailing label to return product.

It is very important that you fill in the requested information on the BRC and return it upon receipt, <u>even if you do not have any of the lot, so that we can verify your receipt of this recall notification.</u> Please order replacement merchandise using normal ordering procedures.

Wholesalers, in addition to completing the enclosed BRC, please also notify those to whom you have distributed this lot and request that they contact Universal Rx Solutions at 1-770-785-9710 choose option 3 at the prompt.

Pharmacies, in addition to completing the enclosed BRC please also notify those patients to whom you have distributed this lot and request that they return their unused and unopened pouch systems directly to you and in turn, you will return the recalled items to: Universal Rx Solutions,** 2084-900 M, Lake Industrial Court, PO Box 998-30012, Conyers, GA 30013-5758. Please see detailed instructions below. Please call 1-770-785-9710 with questions regarding your product return.

1. Patients will bring back pouch systems back to pharmacies and receive replacement product.
   - Replacement of the same number of systems returned does not require additional prescription. Note: In some states a prescription is required. We recommend you make every effort to comply with those state laws or regulations.
   - If the systems are returned to a pharmacy different than the original issuing pharmacy, a prescription is required for replacement.

2. Pharmacies accept the systems from the patients and document receipt with a memo to their 222 file (system type, number received, reason (recall), patient and date).
   - If the receiving pharmacy is not the original issuing pharmacy, this should be noted in the memo.
   - In the latter case, if the identity of the issuing pharmacy is known, it should be noted in the memo.

3. Pharmacies should store returned systems in a manner consistent with how they store other CII drugs, taking appropriate safeguards against inadvertent redispensing.
4. Pharmacies should contact Universal Rx Solutions at 1-770-785-9710 to obtain a 222 form and return kit.
   - Please use the return kit labels and follow all directions included with the kit when making your return.

The Pharmacies will be reimbursed for returned product. This reimbursement will be made by credit memorandum or check.

Specific information to help you respond to questions from your patients is available at www.duragesic.com or www.Janssen.com

If you have additional questions regarding this product recall or require further assistance, please contact Janssen Medical Services Contact Center 1-800-Janssen (1-800-526-7736).

Sincerely,

William Parks
Janssen Pharmaceutica
Director, Trade Relations

** Universal Rx Solutions (USI) is committed to protect the privacy of consumers health information, and to comply with applicable federal and state laws that protect the privacy and security of consumers health information. USI policy establishes the basic requirements for the use or disclosure of consumers' protected health information, consistent with this commitment.