April 7, 2004

URGENT EXPANDED DRUG RECALL NOTIFICATION - PATIENT LEVEL

Subject: DURAGESIC® (fentanyl transdermal system) CII 75 mcg/hour NDC #50458-035-05 Lot Control Numbers 0327192 (exp. 10/05) 0327193 (exp. 10/05), 0327294 (exp. 11/05), 0327295 (exp. 11/05), and 0330362 (exp. 12/05)

Dear Pharmacist:

Janssen Pharmaceutica Products, L.P. would like to inform you of an expanded recall to users of DURAGESIC (fentanyl transdermal system) CII 75 mcg/hour, NDC #50458-035-05, control numbers 0327192 (exp. 10/05), 0327193 (exp. 10/05), 0327294 (exp. 11/05), 0327295 (exp. 11/05) and 0330362 (exp. 12/05).

The company recalled one lot of DURAGESIC 75 mcg/hour patches (control number 0327192) in February 2004 after determining that a small percentage of patches in this lot might leak medication along one edge. Since then, a small number of patches with the same problem have been identified in one additional lot. As a precaution, the company is recalling four additional lots of 75 mcg/hour patches that were produced on the same manufacturing line during the same period.

Exposure to the leaked medication could result in inadvertent ingestion or an increased transdermal absorption of the opiate component fentanyl, leading to potentially life-threatening complications.

Conversely, leakage of medication could lead to inadequate dosing, resulting in treatment failure and/or opiate withdrawal.

Anyone who comes in contact with the leaked medication is advised to rinse exposed skin thoroughly with water only; soap should not be used.

Only control numbers listed above are included in this expanded recall. All other control numbers of DURAGESIC 75 mcg/hour patches and other dosage strengths 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).

Check your stock immediately. If you have any product with control numbers 0327192 (exp. 10/05), 0327193 (exp. 10/05), 0327294 (exp. 11/05), 0327295 (exp. 11/05) and 0330362 (exp. 12/05), **STOP** the distribution of these lots immediately, fill out the included Business Reply Card indicating quantities to be returned, and promptly mail the card to: Universal Rx Solutions, 2084-900 M, Lake Industrial Court, PO Box 998-30012, Conyers, GA 30013-5758.** Once received, Universal Rx Solutions will send a 222 form, instructions and a mailing label to return product. Please allow 2 to 3 weeks for the DEA 222 form and return kit to arrive.

It is very important that you fill in the requested information on the BRC and return it upon receipt, even if you do not have any of these lots, so that we can verify your receipt

of this recall notification. 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 these lots and request that they contact Universal Rx Solutions at 1-800-777-6565 and choose option 6 at the prompt. Do not copy your BRC or provide it to customers – a pharmacy specific BRC will be supplied to pharmacies directly from Universal Rx Solutions. Should customers call requesting information about return of product from affected lots, please direct them to contact Universal Rx Solutions at 1-800-777-6565.

Pharmacies, in addition to completing the enclosed BRC please also notify those patients to whom you have distributed these lots of DURAGESIC 75 mcg/hour patches (control numbers 0327192, 0327193, 0327294, 0327295, and 0330362) right away and request that they return their unused and unopened pouches from these lots directly to you. These lot numbers were distributed from December 15,2003 through March 12, 2004. Please 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 1-800-777-6565 with questions regarding your product return. Do not return recalled product without obtaining a 222 form from Universal Rx Solutions.

1. Patients will bring the unused DURAGESIC patches from recalled lots in unopened pouches back to pharmacies and receive replacement product.

    - Replacement of the same number of DURAGESIC 75 mcg/hour patches from recalled lots may or may not require an additional prescription. Note: In some states, a prescription is required for this substitution. We advise you to check with your state board of pharmacy, drug control division, to verify your local state laws and regulations and comply with them. Pharmacists will be requested to return the patches from the recalled lots to Universal Rx Solutions for a full refund.

    - If DURAGESIC 75 mcg/hour patches from unaffected lots are not available, a suitable substitution should be made, e.g., using either a 50 mcg/hour patch and a 25 mcg/hour patch or three 25 mcg/hour patches. Note: It is anticipated that a new prescription will be required for substitution of other dosage strengths. We advise you to check with your state board of pharmacy, drug control division, to verify your local state laws and regulations and comply with them. Pharmacists are requested to return the patches from recalled lots along with form 222 to Universal Rx Solutions for a full refund.

    - If the patches are returned to a pharmacy different than the original issuing pharmacy, a prescription is required for replacement.

2. Pharmacies should accept the unused and unopened pouches from patients and document receipt with a memo to the pharmacy's 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. If the identity of the issuing pharmacy is known, it should be noted in the memo.

3. Pharmacies should store returned pouches in a manner consistent with how they store other CII drugs, taking appropriate safeguards against inadvertent redispensing.
4. Pharmacists should contact Universal Rx Solutions at 1-800-777-6565 and choose option 6 to obtain a 222 form and return kit.
    - The return kits will provide detailed instructions for returning product from recalled lots and will include pre-paid Fed-Ex labels. Please use the return kit labels and follow all directions included with the kit when making your return.

Pharmacies will be reimbursed for product returned in accordance with this recall. This reimbursement will be made by credit memorandum (direct account) or check (indirect account) 4–6 weeks after receipt of product.

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

Report adverse events and product defects relating to DURAGESIC to Janssen Pharmaceutica Products, L.P. at the contact number listed below or to the FDA MedWatch Program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178), by mail (using postage-paid form to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787) or via www.accessdata.fda.gov/scripts/medwatch.

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

Please see attached Full Prescribing Information, including Boxed Warnings.

Sincerely,

William Parks
Director, Trade Relations
Janssen Pharmaceutica Products, L.P.

** 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.