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Recall -- Firm Press Release

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Actavis Recalls Certain Fentanyl Patches in the US as Precaution

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FOR IMMEDIATE RELEASE -- Morristown, NJ -- February 17, 2008 -- Actavis Inc., the United States manufacturing and marketing division of the international generic pharmaceutical company Actavis Group hf, today announced that 14 lots of Fentanyl transdermal system CII patches sold in the United States by Actavis' subsidiary Actavis South Atlantic LLC are being voluntarily recalled from wholesalers and pharmacies as a precaution.

The recalled patches were manufactured by Corium International Inc., a contract manufacturer for Actavis, and sold nationwide in the United States by Actavis South Atlantic LLC.

Fentanyl patches sold by Actavis in Europe are not affected by this recall.

The 14 lots of Fentanyl transdermal system patches being recalled may have a fold-over defect which may cause the patch to leak and expose patients or caregivers directly to the fentanyl gel. Although unaware of any injuries resulting from this issue Actavis, as a precaution, is recalling these lots. As per the approved product labelling for Fentanyl transdermal system, fentanyl is a potent Schedule II opioid medication. Fentanyl patches that are leaking or damaged in any way should not be used. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal. Anyone who comes in contact with fentanyl gel should thoroughly rinse exposed skin with large amounts of water only; do not use soap. Immediately dispose of affected patches that may be damaged or compromised in any way by flushing them down the toilet, using caution not to handle them directly. Damaged and/or compromised patches that have leaked gel will not provide effective pain relief.

The lots covered by this recall are: 27261 (exp 05/09), 27317 (exp 05/09), 27318 (exp 06/09), 27319 (exp 06/09), 27391 (exp 06/09), 27409 (exp 06/09), 27475 (exp 07/09), 27476 (exp 06/09), 27488 (exp 06/09), 27514 (exp 07/09), 27536 (exp 07/09), 27537 (exp 08/09), 27538 (exp 08/09), 27545 (exp 07/09), covering the following strengths: 25 mcg/hr, 50 mcg/hr, 75 mcg/hr and 100 mcg/hr.

Please note: Actavis South Atlantic LLC was formerly known as Abrika Pharmaceuticals Inc. The pouches containing the patches are labelled with an Abrika Pharmaceuticals label, but the outer carton bears the Actavis logo with the following product names:

Actavis Fentanyl Transdermal System, 25 mcg/hr. NDC 67767-120-18.
Actavis Fentanyl Transdermal System, 50 mcg/hr. NDC 67767-121-18.
Actavis Fentanyl Transdermal System, 75 mcg/hr. NDC 67767-122-18.

Actavis Fentanyl Transdermal System, 100 mcg/hr. NDC 67767-123-18.

Anyone who has fentanyl patches labelled with an Abrika or Actavis label should check them for these lot numbers.

Affected patches should not be handled directly.

Anyone with Actavis Fentanyl transdermal system patches with the above listed lot numbers should call 1 877 422 7452.

Patients using fentanyl patches who have medical questions should contact their health-care providers.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

Fentanyl transdermal system is indicated for the management of persistent, moderate to severe chronic pain that requires continuous, around the clock opioid administration for an extended period of time and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate release opioids.

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