

FDA Bans Unapproved Opioid Analgesics

Important Notice

BACKGROUND

In the interest of public safety, the FDA announced in June 2006, the release of its compliance policy guide indicating the agency's focus on curtailing the release of unapproved medications into the U.S. market. The FDA action detailed in this Advisory is a result of this policy.

Opioid analgesics are the most commonly used medications in workers' compensation due to their use for the treatment of mild, moderate, or severe pain.

NEW DEVELOPMENTS

On March 31, 2009, the FDA informed the public that nine drug manufacturers would be instructed to cease the production of 14 opioid analgesic agents that the agency has classified as "unapproved" medicinal products. The affected products represent various generic formulations of oxycodone, morphine sulfate, and hydromorphone.

The FDA has stated that any previously approved versions of generic morphine sulfate, oxycodone, and hydromorphone will continue to be available to the general public. A number of manufacturers will continue to produce FDA-approved versions of these products. As the supply of unapproved agents decreases, it is possible that supplies of FDA-approved versions of morphine sulfate, oxycodone, and hydromorphone may also become depleted as patients are converted to FDA-approved products. As a result, prices for available products will likely rise, leading to increased drug costs for workers' compensation payors.

The FDA warned manufacturers that they would be subject to disciplinary actions if the production of the recalled agents did not cease within 60 days, and even provided distributors with a slightly longer deadline of 90 days to cease distribution of current stockpiles. The FDA sanction was issued to manufacturers that failed to submit product safety and efficacy data or meet manufacturing process and/or product labeling standards.

IMPACT IN WORKERS' COMPENSATION

This Advisory is intended to notify our clients of the FDA's decision, as it will impact the availability of low-cost generic formulations of certain opioid medications used in the treatment of pain associated with industrial injuries. This situation presents a potential increase to the overall cost of opioid analgesics, the most frequently prescribed class of medications in the workers' compensation industry.

IMPACT TO PAYORS

Overall pharmacy costs are expected to increase across the workers' compensation industry primarily due to the projected increase in the cost of narcotic medications. This increase will occur as a result of the decreased supply of lower-cost generic formulations of the products identified in this Advisory and a shift to higher-cost brand alternatives.

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IMPACT TO INJURED WORKERS

Due to the high utilization of opioid analgesics in workers' compensation, it is possible that a significant number of injured workers may be utilizing one or more of the affected products. Pharmacies will convert these patients to FDA-approved versions of the affected products or work with prescribers to determine appropriate alternatives. **PMSI's Mail Order Pharmacy and Tmesys® network pharmacies will continue to dispense the safest and most cost-effective formulations for injured workers, utilizing generic formulations whenever possible.**

PRODUCTS AFFECTED

The complete list of the FDA-banned medications and their manufacturers is listed below.

Drug Manufacturer	Identified Unapproved Products
Boehringer Ingelheim Roxane Inc.	Roxicodone® Tablets, 5 mg
Roxane Laboratories, Inc.	Hydromorphone Hydrochloride Tablets, 2 mg and 4 mg
Glenmark Generics Inc.	Morphine Sulfate Tablets, 15 mg and 30 mg Morphine Sulfate Immediate Release Oral Solution, 20mg/5ml
Lannett Company, Inc.	Hydromorphone HCl Tablets, 2mg and 4mg
Lehigh Valley Technologies Inc.	Morphine Sulfate Tablets, 15 mg and 30 mg
Physicians Total Care, Inc.	Morphine Sulfate Immediate Release Tablets, 30 mg Hydromorphone Tablets, 2 mg Hydromorphone Hydrochloride Tablets 4 mg
Xanodyne Pharmaceuticals Inc.	Roxicodone® Tablets, 5 mg

Consumers and healthcare professionals can visit http://www.fda.gov/cder/drug/unapproved_drugs/narcoticsQA.htm to view a list of currently available FDA-approved products containing morphine sulfate, oxycodone, and hydromorphone. It is important to note that the current FDA action is NOT a drug recall. Manufacturers and distributors are not required to recall products already on pharmacy shelves; they are required to cease production and distribution of the identified unapproved medications. Unapproved versions of morphine sulfate, oxycodone, and hydromorphone may still be found in pharmacies for a limited period of time.

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175 Kelsey Lane Tampa, FL 33619 PH: 877.ASK.PMSI www.pmsionline.com

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REFERENCES

Questions and Answers for Consumers about FDA's Action Involving Unapproved Narcotics Containing Morphine Sulfate, Hydromorphone, or Oxycodone. U.S. Food and Drug Administration. http://www.fda.gov/cder/drug/unapproved_drugs/narcoticsQA.htm <Accessed April 28, 2009>

FDA Acts to Halt Marketing of Certain Unapproved Prescription Narcotic Drugs Patients Still Have Access to Approved Narcotics for Pain Relief. U.S. Food and Drug Administration. <http://www.fda.gov/bbs/topics/NEWS/2009/NEW01983.html> <Accessed April 28, 2009>

FDA Announces Extension of Enforcement Discretion Related to Morphine Sulfate Oral Solution 20 mg/ml. U.S. Food and Drug Administration. http://www.fda.gov/cder/drug/unapproved_drugs/morphine_extension.htm <Accessed April 28, 2009>