



The Florida Academy of **PAIN MEDICINE** Integration & Innovation

FDA Public Health Advisory on Certain Opiate Products Made for Endo Pharmaceuticals

Medication Mix-Up Possible Due to Packaging Issues; Shortages Expected in Coming Weeks

The U.S. Food and Drug Administration (FDA) is advising healthcare professionals and patients of a potential problem with opiate products manufactured and packaged for Endo Pharmaceuticals by Novartis Consumer Health at its Lincoln, Nebraska, manufacturing site. Due to problems that occurred when these products were packaged and labeled at the site, tablets from one product type may have carried over into packaging of another product. This could result in a stray pill of one medicine ending up in the bottle of another product. The likelihood of this occurring in medication dispensed to patients is estimated to be low.

FDA advises patients and healthcare professionals to examine opiate medicines made by Endo in their possession and ensure that all tablets are the same. **FDA and Endo are providing instructions on how to identify an incorrect tablet in these medicines.**

The following Endo Pharmaceutical products may be affected by the packaging problem (see also: www.endo.com)

- * Opana® ER (oxymorphone hydrochloride) Extended-Release Tablets CII
- * Opana® (oxymorphone hydrochloride) CII
- * Oxymorphone hydrochloride Tablets CII
- * PERCOCET® (oxycodone hydrochloride and acetaminophen USP) Tablets CII
- * PERCODAN® (oxycodone hydrochloride and aspirin, USP) Tablets CII
- * ENDOCET® (oxycodone hydrochloride and acetaminophen USP) Tablets CII
- * ENDODAN® (oxycodone hydrochloride and aspirin, USP) Tablets CII
- * MORPHINE SULFATE Extended-Release Tablets CII
- * ZYDONE® (hydrocodone bitartrate/acetaminophen tablets, USP) CIII

For medications already in homes and pharmacies, there are simple steps (see links below) that patients and healthcare professionals can take to identify whether they have any affected products.

Patients should be advised to follow the instructions provided by FDA and Endo, and look carefully at all of the pills in their pain medicine bottle. (A visual guide to the affected products is available.) For any questions, patients should contact Endo Pharmaceuticals at 1-800-462-3636 or ask their pharmacist or doctor for additional help in identifying whether there are any problems with their medication.

FDA is actively working with Novartis and Endo to address the manufacturing problems. In the coming weeks, they expect there will be periods of shortages for these products. FDA is working with Endo and Novartis to minimize the degree of impact. The degree of shortage will depend upon how quickly safeguards can be put in place to prevent this manufacturing issue from happening in the future and how soon manufacturing can be re-started.

Novartis has initiated a consumer level recall of the other non-opiate products made at their Lincoln, Nebraska, manufacturing facility out of an abundance of caution for these other products. Please see the Novartis Press Release for more information.

FDA will update the public if this situation changes and more information is available.

.....

This advisory is also available on the FDA website.