

INSight Alert

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Ethex Corporation Product Recall – Expanded

On February 3, 2009 ETHEX Corporation, a subsidiary of KV Pharmaceutical, issued a voluntary expansion to the retail level of a previously announced recall on certain products. The recall had been previously issued to the wholesale level, but is now being expanded to the retail level. The affected drug products are listed below:

- Morphine Sulfate Extended-Release
- Morphine Sulfate Immediate-Release
- Dextroamphetamine Sulfate
- Isosorbide Mononitrate Extended-Release
- Propafenone HCl

This is a precautionary measure because these drugs may have been manufactured under conditions that did not sufficiently comply with current Good Manufacturing Practices (cGMPs). Some of these products have had specific lots recalled in December of 2008 due to defects found, including oversized tablets delivering higher than labeled doses. These additional products are being removed to assure that no other defective products remain in the marketplace.

It is important to note that only those products manufactured by ETHEX Corporation have been recalled. Other formulations of these generic medications are still available from various other manufacturers.

Members who may have these recalled medicines in their possession should continue to take them in accordance with their prescriptions, as the risk of suddenly stopping needed medication may place patients at risk. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these products, or to obtain replacement medications or prescriptions.

Questions about the recall should be addressed to ETHEX Customer Service at 1.800.748.1472, faxed to ETHEX Customer Service at 314.646.3788, or e-mailed to customer-service@ethex.com.

In response to this event, FutureScripts/FutureScripts Secure is:

- Posting a point-of-sale (POS) message to retail pharmacists. Claims for any of the affected drugs will reject at the point of sale with the following message: “NDC NOT ON FILE”.
- Overriding refill-too-soon rejections for members needing replacement medications
- Posting a Web Alert for our members and providers on www.futurescripts.com

References:

Food and Drug Administration website. Available at www.fda.gov. Accessed February 4, 2009.