

NATIONAL PBM COMMUNICATION

ETHEX Corporation Initiated Nationwide Voluntary Recalls of Specific Lots of Five Generic Products Due to the Potential for Oversized Tablets

November 10, 2008

**Propafenone HCl Tablets (150 mg, 225 mg, and 300 mg)
Isosorbide Mononitrate Extended Release Tablets (30 mg and 60 mg)
Morphine Sulfate Extended Release Tablets (15 mg)
Morphine Sulfate Immediate Release Tablets (15 mg and 30 mg)
Dextroamphetamine Sulfate Tablets (10 mg)**

ETHEX Corporation announced today that it has voluntarily recalled to the consumer level specific lots of five generic/non-branded products that it markets. These lots have been recalled as a precaution, due to the possibility that they may contain oversized tablets. Oversized tablets may contain more than the intended levels of the active drug ingredient, which could result in patients receiving as much as about twice the expected dosage of these drugs. The concern with oversized tablets in the affected lots relate to potential overdoses of Propafenone HCl, Isosorbide Mononitrate, Morphine Sulfate and Dextroamphetamine Sulfate that can have serious or life-threatening consequences.

The facilities are required to determine whether the affected lot numbers (refer to lot numbers and expiration dates provided below) were dispensed to the patient and if so, identify the patients who may have received the affected product and contact the patient by phone to provide instructions on how to obtain a new supply of medication and return the medication being recalled. Patients who received Propafenone or Isosorbide Mononitrate that are unable to be contacted by phone, will be mailed a replacement supply of medication with the respective Patient Letter (see Attachments). Patients who received Morphine Sulfate or Dextroamphetamine that are unable to be contacted by phone, will be mailed the respective Patient Letter (see Attachments) with instructions on how to obtain a replacement supply of medication. All remaining product with the affected lot numbers at the facility/CMOP level should be returned as instructed **[include instructions]**.

Patients should be advised to contact their Healthcare Provider or seek medical care if symptoms of an overdose develop. Any adverse reactions experienced with the use of these products, and/or quality problems may 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.

[ETHEX Corporation Initiated Nationwide Voluntary Recalls of Specific Lots of Five Generic Products Due to the Potential for Oversized Tablets \(November 7\)](#)

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**Propafenone HCl Tablets - 150 mg, 225 mg, and 300 mg
Isosorbide Mononitrate Extended Release Tablets – 30 mg and 60 mg
Morphine Sulfate Extended Release Tablets - 15 mg
Morphine Sulfate Immediate Release Tablets - 15 mg and 30 mg
Dextroamphetamine Sulfate Tablets - 10 mg**

Contact:

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FOR IMMEDIATE RELEASE -- St. Louis, MO- November 7, 2008 – ETHEX Corporation announced today that it has voluntarily recalled to the consumer level specific lots of five generic /non-branded products that it markets. These lots have been recalled as a precaution, due to the possibility that they may contain oversized tablets. Oversized tablets may contain more than the intended levels of the active drug ingredient, which could result in patients receiving as much as about twice the expected dosage of these drugs.

Overdoses of Propafenone HCl, Isosorbide Mononitrate, Morphine sulfate and Dextroamphetamine Sulfate can have serious or life-threatening consequences. In the case of Propafenone HCl, these consequences can include arrhythmias (irregular heartbeat) and low blood pressure. In the case of Isosorbide Mononitrate, these consequences can include fainting and low blood pressure. In the case of Morphine Sulfate, these consequences can include respiratory depression (difficulty or lack of breathing) and low blood pressure. In the case of Dextroamphetamine Sulfate, these consequences can include rapid heart rate and high blood pressure.

The lots involved in the recall were all shipped prior to May 22, 2008 and are as follows:

Propafenone HCl Tablets, 150 mg: Lots: 73761, 78184, 79373, 81240, 81241, 81242, 83470, 84357, 90525, and 90526 with expiration dates ranging from 3/2009 to 3/2011

Propafenone HCl Tablets, 225 mg: Lots: 71720, 74831, 76014-15, 81243-45, 89731, 90527-29, and 90657 with expiration dates ranging from 3/2009 to 2/2011

Propafenone HCl Tablets, 300 mg: Lots: 72834, 76016-18, 81246, 89092, 89732, 90530, 90532, and 91641-42 with expiration dates ranging from 6/2009 to 3/2011

Isosorbide Mononitrate Extended Release Tablets, 30 mg: Lots: 62355, 66423, and 68102 with expiration dates ranging from 11/2008 to 8/2009

Isosorbide Mononitrate Extended Release Tablets, 60 mg: Lots: 63466, 66034, 67351, and 67354 with expiration dates ranging from 12/2008 to 11/2009

Morphine Sulfate Extended Release Tablets, 15 mg: Lots: 81175, 82514-16, 89660, 89664, 89667, 90249-51, and 91687 with expiration dates ranging from 12/2008 to 2/2010

Morphine Sulfate Immediate Release Tablets, 15 mg: Lots: 77852-54, 81746, 82519-20, 84113, and 90276-78 with expiration dates ranging from 9/2009 to 1/2011

Morphine Sulfate Immediate Release Tablets, 30 mg: Lots: 75093, 77855-57, 82297, 82521-22, 87239, 88925, and 90288-98 with expiration dates ranging from 8/2009 to 3/2011

Dextroamphetamine Sulfate Tablets, 10 mg: Lots: 73934, 75892, 77945, 81137, 86320 with expiration dates ranging from 6/2009 to 5/2011

The 150 mg Propafenone Hydrochloride Tablets is a white, scored round film coated tablet with "ETH" on one side and "331" with a bisect on the reverse. The 225 mg Propafenone Hydrochloride Tablets is a white, scored round film coated tablet with "ETH" on one side and "332" with a bisect on the reverse. The 300 mg Propafenone Hydrochloride Tablets is a white, scored round film coated tablet with "ETH" on one side and "333" with a bisect on the reverse.

The 30 mg Isosorbide Mononitrate Extended Release Tablet is an oval, reddish-pink, film-coated tablet with a debossed "E" bisecting "30" on one side and bisect on the other side. The 60 mg Isosorbide Mononitrate Extended Release Tablet is an oval, yellow film-coated tablet with a debossed "E" bisect "60" on one side and bisect on the other side.

The 15 mg Morphine Sulfate Extended Release Tablet is a green oval tablet with "15" on one side and an "E" on the reverse. The 15 mg Morphine Sulfate Immediate Release Tablet is a round brown tablet with a "15" on one side and an "ETH" on the reverse. The 30 mg Morphine Sulfate Immediate Release Tablet is a capsule shaped brown tablet with "30" on one side and an "ETHEX" on the reverse.

The 10 mg Dextroamphetamine Sulfate Tablet is a round, flat-face, bevel edge, orange mottled tablet debossed "ETHEX" and "312" on one side and double-scored on the other side.

ETHEX Corporation has initiated recall notifications to wholesalers and retailers who have received any inventory of the recalled product lots with instructions for returning the recalled products. The notification also includes instructions for the retailers/pharmacies to contact consumers who were dispensed these drugs for replacement of the product and/or refund. If the wholesalers and retailers have not already done so, they are urged to contact the number below regarding procedures for returning the recalled products. If consumers have any questions about the recall, they should call the number listed below for customer inquiries, their physician, their pharmacist or other health care provider.

Consumers who experience any adverse reactions to these drugs should contact their physician and/or healthcare provider immediately.

Any customer inquiries related to this action should be addressed to ETHEX Customer Service at 1-800-748-1472, or fax to ETHEX Customer Service at 314-646-3751 or sent

via email to: customer-service@ethex.com with representatives available Monday through Friday, 8:00 am to 5:00 pm Central Standard Time (CST).

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Any adverse reactions experienced with the use of these products, and/or quality problems may 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.