



*Innovative Pharmaceuticals Offering Therapeutic Excellence*

January 28, 2009

**URGENT PRODUCT RECALL**

Dear Recall Coordinator:

**Product:**

Ther-Rx Corporation is voluntarily recalling all lots within expiration of Gynazole-1<sup>®</sup>, Clindesse<sup>®</sup> and microK<sup>®</sup> Extencaps<sup>®</sup> 8mEq and microK<sup>®</sup> Extencaps<sup>®</sup> 10mEq because they may potentially have been manufactured under conditions that did not fully comply with cGMP's. This recall involves the following NDC's only:

Gynazole-1<sup>®</sup>, NDC 64011-0001-08

Clindesse<sup>®</sup>, NDC 64011-0124-08

microK<sup>®</sup> Extencaps<sup>®</sup> 8mEq 100, NDC 64011-0010-04

microK<sup>®</sup> Extencaps<sup>®</sup> 8mEq UD, NDC 64011-0010-11

microK<sup>®</sup> Extencaps<sup>®</sup> 8mEq 500, NDC 64011-0010-08

microK<sup>®</sup> Extencaps<sup>®</sup> 10mEq 100, NDC 64011-0009-04

microK<sup>®</sup> Extencaps<sup>®</sup> 10mEq UD, NDC 64011-0009-11

microK<sup>®</sup> Extencaps<sup>®</sup> 10mEq 500, NDC 64011-0009-08

**Level:**

**This recall is being carried out to the wholesale level.**

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

**Action for Distributor:**

**Distributor**

- Stop distributing the affected lots. **Quarantine product immediately.**
- Please perform a physical count and record this data on the response letter which is included.
- Send back the response letter even if you do not have any product to:  
Ther-Rx Corporation  
Email: [info@ther-rx.com](mailto:info@ther-rx.com) or fax to **(314) 646-3701**



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- Notifications of this recall are being sent to direct wholesale customers of Ther-Rx Corporation. For customers who redistribute the products to other wholesale customers, please notify them to contact Capital Returns 1-888-851-3502 to receive recall product return packet and instructions.

- Recalled product must be returned to:

**Capital Returns**  
**6101 North 64<sup>th</sup> Street**  
**Milwaukee, WI 53218**  
**1-888-851-3502**

**Please mark all returned containers “RECALL” and a numbered debit memo must be included.**

**A copy of the debit memo must be sent to the following address:**

Ther-Rx Corporation  
Attn: Tammy Butler  
One Corporate Woods Drive  
Bridgeton, MO 63044

**Do not return product until you have contacted Capital Returns for a recall product return packet instructions.**

You will be credited for the returned product, the appropriate processing fees and shipping costs associated with this recall. Any customer inquiries related to this action should be addressed to Capital Returns Customer Service at Phone 1-888-851-3502, with representative's available Monday through Friday, 8 am to 6 pm EST.

Sincerely,

David Kaiser  
Senior QA Manager, Compliance  
Recall Coordinator



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**PRODUCT RECALL – Response Letter**

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We have reviewed our inventory (check one):

- No units were detected in our inventory
- Yes, one or more units were detected in our inventory

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Company: \_\_\_\_\_ DEA License: \_\_\_\_\_

Address: \_\_\_\_\_ City, State: \_\_\_\_\_

Phone #: \_\_\_\_\_ Date: \_\_\_\_\_

**Please fax to Ther-Rx 314-646-3701 or e-mail to Ther-Rx Customer Service at [info@ther-rx.com](mailto:info@ther-rx.com).**