

**URGENT ACTION REQUIRED
HEARTLAND K-LOT PRODUCT RECALL**

Heartland Repack Services is clearing up remaining issues surrounding the recall of all products with lot numbers beginning with the letter "K". This recall commenced on August 1, 2006 due to the possible mislabeling of product packaging. This questionnaire addresses possible K-lot product that has not been recovered yet. This questionnaire requires your prompt and accurate attention.

Please re-inspect as indicated below and provide responses immediately, but no later than Wednesday, October 25, 2006. If your responses are not complete by the due date, please provide: information then available; identify the information still being collected; and, the date by which outstanding information will be provided.

**E-MAIL ALL COMPLETED INFORMATION TO:
DAVID BRICKER – dbricker@hhstol.com**

Wherever additional space is needed create extra pages in this document.

Name and address of pharmacy responding:

Name _____
Address _____

1. Have you re-inspected your pharmacy inventory for K-lot product?

Yes _____ No _____

When _____ Who _____

2. Have you checked all E-Kits, Convenience Boxes, or other similar stock, both in facilities and in stock at the pharmacy, for K-lot products?

Yes _____ No _____

When: _____ Who _____

3. Did you find any K-lot product in any E-Kits, Convenience Boxes, or other similar stock? Yes _____ No _____

When: _____

If yes, has it been removed? Yes _____ No _____

When: _____ By whom: _____

If yes, has it been returned to HRS? Yes _____ No _____

When _____ Who _____

4. Have you checked all storage bins into which boxes and bags are emptied for K-lot products?
Yes _____ No _____

When: _____ Who _____

5. Did you find any K-lot product in any storage bins into which boxes and bags are emptied? Yes _____ No _____

When: _____

If yes, has it been removed? Yes _____ No _____

When: _____ By whom: _____

If Yes, has it been returned to HRS? Yes _____ No _____

When _____ Who _____

6. Do any of the facilities served by your pharmacy have patients who reside other than in the facility? Yes _____ No _____

If yes, have the patients been notified of the K-lot recall? Yes _____
No _____

When: _____ By whom: _____

If the patient has not been contacted yet, please contact the patient and advise Heartland of any K-lot product recovered from such patient and when it was recovered.

7. Have any patients been discharged **with medications** from any of the facilities that you serve? Yes _____ No _____

If so:

Have you or the facility contacted, the patient(s) to determine whether they have K-lot product? Yes _____ No _____

When _____ By whom: _____.

If the patient has not been contacted yet, please contact the patient and advise Heartland of any K-lot product recovered from such patient and when it was recovered.

8. Did you receive K-lot product transferred or purchased from another pharmacy?
Yes _____ No _____

When _____ From whom: _____

If yes, is this product considered in your answers to all questions?

Yes_____ No_____

When_____

If not, all questions must be answered considering this product.

9. If you have identified any K-lot product in response to any of these questions, please indicate what drug product is involved, what lot numbers are involved, the quantity identified, when it was distributed, and to whom.

10. Are you aware, either from information from pharmacy personnel or facilities which you serve, of any injuries or illnesses associated with the use of any K-lot product, and, if so, describe the product, the injuries/illnesses, the dates when you learned this information, and any other information about the cause or severity of the injuries/illnesses.

11. Are you aware of any K-lot that was actually mislabeled or mispackaged? If so, provide all details you can about the product.

Create additional pages within this document if more space is needed to respond.

Please identify all individuals who contributed to your responses:

All K-lot product must be returned to:

**Heartland Repack Services
Attention: Joyce Gregory
302 S. Byrne Road, Building 200
Toledo, OH 43615**

Send by Federal Express, UPS, or similar carrier.

You must retain the tracking information. Please list below the products and quantities of each being returned or PDF your normal return authorization form. Your return authorization number for the K-lot product is RA1007486.

Once again, if you cannot complete these checks and activities by the due date, please provide the information that you have available, and advise what is still in progress and when it will be completed.

PLEASE NOTE: Your responses will be made available to the Food and Drug Administration. Your pharmacy may be visited by the FDA in order to interview you and confirm your responses.

Respondent: _____ **Title:** _____
Date: _____ Cell Phone # _____

If there are additional questions please contact David Bricker at 1 800 270-6351 ext 6002 or 740 816-7154 (Cell)