

**To:** DC Managers  
**From:** Cynthia Gaw  
**Date:** November 3, 2010  
**RC:** 10-197

**URGENT!!! DRUG RECALL!!! URGENT!!!**

**FDA/SUPPLIER CLASS OF RECALL:** Not Yet Classified  
**LEVEL OF NOTIFICATION:** Wholesale  
**SUPPLIER:** Monarch/King # 30199

Description	Lot #	Exp Date	NDC	UPC	Econo #
EMBEDA CAP 80/3.2MG 100	458K91	07/2011	60793043501	36079343501	1211671
	459K91	07/2011			

King Pharmaceutical Inc is voluntarily recalling the above lots because during stability testing it yielded an out of specification dissolution result at the three month time point. This recall is to the Wholesale level. Product started shipping February 2010.

Please check your inventory for the above lots. Complete and return the business reply card to Stericycle within five business days, even if you do not have the affected lots. Upon receipt of your complete Business Reply card, Stericycle will forward to you a Product Return Package, including a DEA 222 form, Packing Slip and prepaid UPS labels. A complete DEA 222 form is required to process your return. Return affected product to the address below with the complete packing slip and using the prepaid labels.

Stericycle  
2670 Executive Dr., Suite A  
Indianapolis, IN 46241

McKesson Distribution Centers are unable to accept returns of controlled substances unless the product is sealed, unbroken and in original manufacturer container. Customers need to return product directly to the Supplier or Supplier designee. DC's need to receive return instructions and DEA Form 222 for Class II controlled drugs from Supplier before returning.

If you have additional question concerning this recall or need a reply card, contact Stericycle at 877-496-5043.

This recall is being conducted with the knowledge of the FDA.

**Information contained in this document was provided by Monarch/King.**

**FOR McKESSON USE ONLY:**

- Please follow Recall Guidelines as outlined in the Reclamation SOP for a CLASS III RECALL.
- PROCESS TO THE WHOLESALE LEVEL.