URGENT DRUG RECALL

Product	*NDC Number*	*Lot**	*Expiration Date*
Propofol Injectable Emulsion, 1%, 1 g / 100 mL (10 mg/mL)	**0409-4699-24**	**03-388-DJ**	**1MAR2013**
Propofol Injectable Emulsion, 1%, 200 mg / 20 mL (10 mg/mL)	**0409-4699-30**	**04-515-DJ**	**1APR2013**
		06-802-DJ	**1JUN2013**
		93-857-DJ	**1SEP2012**
		93-896-DJ	**1SEP2012**
Propofol Injectable Emulsion, 1%, 500 mg / 50 mL (10 mg/mL)	**0409-4699-33**	**01-175-DJ**	**1JAN2013**
		04-565-DJ	**1APR2013**

* Note: the lot number may be followed by 01 or 02

August 29, 2012

Dear Valued Customer:

Hospira, Inc. is voluntarily recalling seven lots of Propofol Injectable Emulsion identified above due to a single visible particulate identified during a retain sample inspection. In the unlikely event where particulate matter is injected into a patient, there may be the potential for patient injury where medical intervention may be required.

These lots were distributed November 2010 to December 2011. Hospira has not received reports of any adverse events associated with this issue for these lots. This recall is being conducted as a precautionary measure. Hospira has notified the U.S. Food and Drug Administration.

Hospira has initiated an investigation to determine the root cause and preventive actions.

Please check your inventory and immediately quarantine any affected product. Complete the attached reply form and return it to the fax number or e-mail address on the form, even if you do not have the affected product. Inform healthcare professionals in your organization of this recall.

Return affected product to Stericycle using the label provided with this letter. If you have not received a return label or require additional assistance contact Stericycle at 1-877-722-7554 between the hours of 8am to 5pm ESDT, Monday through Friday. To ensure proper and timely credit, follow the instructions on the return label for returning the product. Please visit http://expertezlabel.com to request additional labels for returning affected product.

If you have distributed the product further, notify your accounts that received the product identified above of this recall and ask them to contact Stericycle to receive a reply form and return labels for returning the product.

Please contact Hospira Customer Care at 1-877-946-7747 or your Hospira representative for information regarding product availability.

Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (8am-5pm CST, M-F) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 or medcom@hospira.com (Available 24 hours a day/7 days per week)	Medical inquiries

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax.

- **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail**: use postage-paid, pre-addressed form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178

Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and we regret any inconvenience this action may cause.

Sincerely,

Janet Stevens
Vice President, Parenteral Quality Operations

Urgent Drug Recall Reply Form – Response Required
NDC 0409-4699-24; NDC 0409-4699-30; NDC 0409-4699-33 Propofol Injectable Emulsion
August 29, 2012

Hospira

Check your inventory and complete the information below, even if you do not have the affected product.
Failure to complete all sections of this page may result in improper, delayed or denied credit.

Fax the completed form to **1-888-628-0727** or e-mail the completed form to **Hospira8717@stericycle.com**.
Please visit http://expertezlabel.com to request additional labels for returning affected product.
If you have not received a return label or require additional assistance contact Stericycle at **1-877-722-7554** between the hours of 8am to 5pm ESDT, Monday through Friday.

Required Information

Business Name _____ Phone Number _____

Address/City/State/Zip _____ DEA # _____

Hospira Customer Number (ship to #) if applicable _____ Your reference # (e.g. PO, Debit Memo or Invoice #) _____

Completed by: Printed Name/Signature/Date _____

☐ I have NO affected product (fill out and return this form to Stericycle at the fax/e-mail above).

☐ **YES**, I have affected product (fill out and return this form to Stericycle via the fax/e-mail above and return the product per the instructions on the return label).

If affected product is not being returned, please explain:

✓ Have you distributed the product further to the retail level? YES___ NO___

✓ If yes, have you notified your retail customers? YES___ NO___ (if no, explain below)

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Urgent Drug Recall Reply Form – Response Required
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NDC and Lot Number	Quantity to be returned	Wholesaler/Distributor Name If you purchased from Wholesalers/Distributors include name, address, city, state, zip, quantity from each, and invoice number. If you purchased directly from Hospira leave this section blank.	PO, debit memo or invoice
0409-4699-24 03-388-DJ*		1.	
		2.	
0409-4699-30 04-515-DJ*		1.	
		2.	
0409-4699-30 06-802-DJ*		1.	
		2.	
0409-4699-30 93-857-DJ*		1.	
		2.	
0409-4699-30 93-896-DJ*		1.	
		2.	
0409-4699-33 01-175-DJ*		1.	
		2.	
0409-4699-33 04-565-DJ*		1.	
		2.	

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