



**MEDICAL SUPPLY BULLETIN**  
HHS SUPPLY SERVICE CENTER  
PERRY POINT, MD 21902

***We Service the World***

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Steven Pearson, Director

David Wernek, Q.A. Specialist, Editor

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BULLETIN NO. 9

April 27, 2011

## **VOLUNTARY DRUG RECALL**

Dear Valued Customer:

This is to notify you that all unexpired lots (listed below) of Dexamethasone Sodium Phosphate Injection, USP, 4mg/ml, 1ml Single Dose Vial, NDC # 0517-4901-25; 5ml Multiple Dose Vial, NDC # 0517-4905-25; and 30 ml Multiple Dose Vial, NDC # 0517-4930-25, distributed by American Regent, Inc., are the subject of a voluntary recall by Luitpold Pharmaceuticals, Inc., as the manufacturer. The recall was initiated because some vials of these lots either contain particulates or have the potential to form particulates prior to their respective expiration dates.

Potential adverse events after intravenous administration of solutions containing particulates may include disruption of blood flow within small blood vessels in the lung, localized inflammation (swelling and redness due to accumulation of inflammatory cells), and granuloma formation. Intramuscular administration could result in foreign body inflammatory response, with local pain, swelling and possible long term granuloma formation.

Dexamethasone Sodium Phosphate Injection, USP is a synthetic adrenocortical steroid used to treat a variety of inflammatory and allergic conditions

The following lots are under Voluntary Recall.

### **Dexamethasone Sodium Phosphate Injection, USP**

(1) 1 ml Single Dose Vial, NDC # 00517-4901-25. **NSN 6505-00-944-4126.**

Lot No(s): 9153, 9170, 9182, 9218, 9254, 9295, 9329, 9352, 9368, 9385, 9422, 9425, 9441, 9512, 9549, 9565, 9605, 9615, 9615A, 9656, 9668, 9690, 9710, 9722, 9743, 0135, 0138, 0164, 0215, 0229, 0245, 0271, 0277, 0282, 0296, 0302, 0305, 0324, 0331, 0342, 0409, 0444, 0593, 0599, 0639, 0678, 0710, 0736, 0773, 0792, 0803, 0819, 0836, 0846, 0853, 0879.

(2) 5 ml Multiple Dose Vial, NDC # 00517-4905-25. **NSN 6505-01-492-6420.**

Lot No(s): 9210, 9250, 9335, 9393, 9417, 9516, 9571, 9620, 9667, 0157, 0217, 0269, 0317, 0392, 0404, 0407, 0556, 0624, 0704, 0765, 0805, 0878, 1055.

(3) 30 ml Multiple Dose Vial, NDC # 00517-4930-25.

Lot No(s): 0213, 0306, 0387, 0565, 0679, 0771, 0840.

We ask for your cooperation in taking the following action:

- Please examine your inventory immediately for the affected lots with the list provided. If you have the recalled product in question immediately cease distribution/use.
- If the Dexamethasone Sodium Phosphate Injection was purchased from SSC, fill out the enclosed **Return Response Form** and send with recall product.
- Mark the returned product "**Recall Materials Enclosed,**" and return to:

**HHS Supply Service Center  
Building 14  
Perry Point, MD 21902**

- Return the affected product before **May 27, 2011** for credit. Accounts will be credited upon receipt of the recalled product. Please note customers must reorder the Dexamethasone Sodium Phosphate Injection.

If you have any questions about this recall, please contact David Wernek, Quality Assurance Specialist at 1-800-642-0263 ext. 1130. We apologize for any inconvenience and appreciate your prompt attention to this recall.

  
Steven Pearson

# Recall Response Form HHS Supply Service Center

Dexamethasone Sodium Phosphate Injection has been identified as being stocked by HHS Supply Service Center. This product is distributed by American Regent, Inc., and manufactured by Luitpold Pharmaceuticals, Inc.

## Dexamethasone Sodium Phosphate Injection NSN 6505-00-944-4126 and NSN 6505-01-492-6420

Point of Contact (POC): \_\_\_\_\_.

Customer Number: \_\_\_\_\_.

Telephone Number: \_\_\_\_\_.

Organization: \_\_\_\_\_.

Date: \_\_\_\_\_.

Product Description	Quantity Disposed
Dexamethasone Sodium Phosphate Injection NSN 6505-00-944-4126 and NSN 6505-01-492-6420	

Please place a copy of the "Recall Response Form" with the return drug product shipment and FAX copy to 410-642-2616, attention Quality Assurance. Mark the returned product if purchased from SSC: **"Recall Materials Enclosed"**, and return to:

**HHS Supply Service Center  
Building 14  
Perry Point, MD 21902**

The recalled product must be received by or before **May 27, 2011** to expedite credit of your Dexamethasone Sodium Phosphate Injection.