



One Luitpold Drive, P.O. Box 9001, Shirley, New York 11967
(631) 924-4000 • (800) 645-1706 • Fax (631) 924-1731

July 24, 2006

VIA EMAIL OR FACSIMILE

URGENT: NOTIFICATION OF VOLUNTARY RECALL

RE: Hydralazine HCl Injection, USP
Strength: 20 mg/mL
Size: 1 mL single dose vials
NDC#: 0517-0911-25
Lot #: 5561 NO

Attention: Pharmacy Buyer/Director

Dear Sir or Madam:

This is to notify you that one lot of the above product, distributed by American Regent, Inc., is the subject of a voluntary Recall by Luitpold Pharmaceuticals, Inc., as the manufacturer. Recall of this product was initiated because some vials may contain particulates.

This lot labeled with a NOVAPLUS® label is under voluntary Recall by all accounts to the USER LEVEL:

| Hydralazine HCl Injection, USP | |
|---------------------------------------|------------------------|
| Lot # | Expiration Date |
| 5561 NO | December, 2006 |

Further use or distribution of this lot of product should cease.

You are hereby instructed to isolate your inventory of the above lot number of Hydralazine Hydrochloride Injection, USP.

Please acknowledge receipt of this recall notification within 24 hours. In addition, notify quantities on hand, if any, by completing the attached Word document and return the document electronically or via facsimile at 631-924-9243.

This Recall requires the return of product to American Regent, Inc. by all accounts to the user level. As a direct account, please return product in inventory. We request that you notify your customers, who purchased lot # 5561NO (NDC # 0517-0911-25) after October 21, 2005, of this Recall and have them return product directly to our Shirley, New York facility. American Regent, Inc. will be responsible for all shipping costs incurred by you or your customers.

American Regent's Customer Service Department will reply electronically or verbally with a Return Authorization number for your shipment of returned product.

We will arrange for the product to be returned to our Shirley, New York facility. Please prepare the shipment as follows:

American Regent, Inc.
26 Precision Drive
Shirley, NY 11967
Attention: Shipping Department
RA # (to be issued)

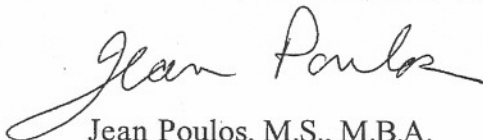
A credit will be issued to your account. If you have any questions or problems regarding this matter, please contact the Director of Customer Service at (631) 924-4000, ext. 142.

This activity previously described is being performed with the knowledge of the U.S. Food and Drug Administration.

Your cooperation is appreciated.

Sincerely,

LUITPOLD PHARMACEUTICALS, INC.



Jean Poulos, M.S., M.B.A.
Vice President of Quality & Regulatory Operations