



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

August 11, 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#: 0517-0901-25

Lot#(s): 5411, 5457, 5552, 5647, 5669, 5753, 6411

NDC#: 0517-0911-25

Lot#(s): 5411NO, 5457NO, 5669NO, 5710NO, 5784NO, 5797NO, 6411NO

Attention: Pharmacy Buyer/Director

Dear Sir or Madam:

This is to notify you that lots 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.

These lots are under voluntary Recall by all accounts to the USER LEVEL:

Hydralazine HCl Injection, USP		
Novaplus® Label	Expiration Date	First Sale Date
Lot #5411NO	September, 2006	August 11, 2005
Lot #5457NO	November, 2006	September 20, 2005
Lot #5669NO	January, 2007	December 27, 2005
Lot #5710NO	February, 2007	January 11, 2006
Lot #5784NO	June, 2007	March 24, 2006
Lot #5797NO	June, 2007	May 30, 2006
Lot #6411NO	December, 2007	August 7, 2006

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Hydralazine HCl Injection, USP		
American Regent Label	Expiration Date	First Sale Date
Lot #5411	September, 2006	August 23, 2005
Lot #5457	November, 2006	September 20, 2005
Lot #5552	December, 2006	October 17, 2005
Lot #5647	January, 2007	November 16, 2005
Lot #5669	January, 2007	December 14, 2005
Lot #5753	March, 2007	February 28, 2006
Lot #6411	December, 2007	July 18, 2006

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

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

Please acknowledge receipt of this recall notification by completing the attached form. The form may also be accessed at www.americanregent.com/recall/hydralazine.asp Please return the form 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 the above lots based on distribution date listed above by sending a copy of this letter and form, and have them return the form and 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 Recall
RA # (to be issued)

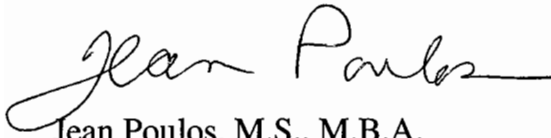
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A credit will be issued to your account. If you have any questions or problems regarding this matter, please contact Customer Service at (800) 645-1706.

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

Your cooperation is appreciated.

Sincerely,

A handwritten signature in cursive script that reads "Jean Poulos". The signature is written in black ink and is positioned above the printed name and title.

Jean Poulos, M.S., M.B.A.

Vice President, *Quality & Regulatory Operations*