Wyeth Pharmaceuticals
P. O. Box 8299
Philadelphia, PA 19101-8299

Wyeth

April 29, 2002

URGENT-DRUG RECALL – Particulates

PRODUCT: Heparin Sodium Injection, USP (Porcine Derived) 1,000 units per mL
SIZE: 25 x 1 mL DOSETTE® Vial/1 mL DOSETTE® Vial
NDC: 0641-0391-25(Shelf Pack)/0641-0391-21(Individual Vial)
LOT NOS.: **ALL** Lots
DISTRIBUTION: August, 1999 – April, 2002

PRODUCT: Heparin Sodium Injection, USP (Porcine Derived) 1,000 units per mL
SIZE: 25 x 10 mL Multiple Dose Vials/10 mL Multiple Dose Vial
NDC: 0641-2440-45(Shelf Pack)/0641-2440-41(Individual Vial)
LOT NOS.: **ALL** Lots
DISTRIBUTION: May, 1999 – March, 2002

PRODUCT: Heparin Sodium Injection, USP (Porcine Derived) 1,000 units per mL
SIZE: 25 x 30 mL Multiple Dose Vials/ 30 mL Multiple Dose Vial
NDC: 0641-2450-45(Shelf Pack)/0641-2450-41(Individual Vial)
LOT NOS.: **ALL** Lots
DISTRIBUTION: May, 1999 – March, 2002

TO: Wyeth Pharmaceuticals/ESI Lederle Customers

Wyeth Pharmaceuticals and ESI Lederle are voluntarily recalling **ALL lots** of Heparin Sodium Injection, USP (Porcine Derived) 1,000 units per mL, 1 mL DOSETTE® Vial, 10 mL and 30 mL Multiple Dose Vials due to clear crystals containing an antioxidant compound from the vial rubber closures being observed during routine retain sample testing. You should extend this recall to the hospital, pharmacy and physician shelf level.

Please examine your Wyeth Pharmaceuticals/ESI Lederle inventories of Heparin Sodium Injection, USP (Porcine Derived) 1,000 units per mL, 1 mL DOSETTE® Vial, 10 mL and 30 mL Multiple Dose Vials immediately, and follow the appropriate course of action described below.

1. If you have any product from the above mentioned NDC numbers, please remove it immediately from sale or use. If you have product to return, please contact Universal RX Solutions of Georgia (USI) at 1-800-777-6565 and choose Option #1 for Customer Service. USI will subsequently send you a Return Authorization Form, a preprinted shipping label(s), and instructions for returning the recalled

product. You will receive credit for the returned merchandise, and you will be reimbursed for the shipping charges.

2. If you have distributed any product to subordinate accounts, please notify them of this recall and request return of the products to you for your return to USI. Please contact USI at 1-800-777-6565 and choose Option #1 for instructions for returning the recalled products you receive from your subaccounts. This recall is to be extended to all hospital, pharmacy and physician/dispensing level accounts.

3. Please mark the appropriate box or boxes on the enclosed pre-paid postcard, record the quantity you will return, and send the postcard to us immediately. Your response, even if you do not have any recalled product, is very important to both us and the FDA in monitoring the effectiveness of this recall.

Additionally, to cover administrative costs you will be reimbursed at the rate of $2.52 per package (full or partial) for the recalled lots. This reimbursement applies only to the recalled lots. The $2.52 is the recommended Healthcare Distribution Management Association (HDMA), reimbursement level for administrative costs involved in a recall.

The Food and Drug Administration has full knowledge of this recall. Wyeth Pharmaceuticals apologizes for any inconvenience resulting from this recall. If you have any questions, please call our Product Quality Department at 1-800-999-9384. Thank you for your cooperation.

Sincerely,

Anil Sawant, Ph.D.
Assistant Vice President
Quality Assurance

Enclosure: Prepaid Postcard