October 5, 2000

URGENT DRUG RECALL

Product Contamination with Acebutolol Hydrochloride

PRODUCT:	*Etodolac Capsules 300 mg*
SIZE:	*Bottle of 100 Capsules*
MANUFACTURER:	*ESI Lederle*
NDC:	*59911-3607-1*
LOT NO.:	*9991052*
EXPIRATION DATE:	*7/02*
DISTRIBUTION:	*October 18, 1999 through August 31, 2000*

Dear Pharmacist,

ESI Lederle is voluntarily recalling its Etodolac Capsules 300 mg **Lot number 9991052**, *which is in bottles of 100. We are extending this recall to the user/patient level. Etodolac is a nonsteroidal anti-inflammatory drug. Some capsules from* **Lot number 9991052** *may contain a variable and unknown quantity of acebutolol hydrochloride, a selective beta blocker used for treating patients with hypertension and ventricular arrhythmias. The maximum amount of acebutolol that could be contained in a capsule of that size is 404 mg.*

The administration of a cardioselective beta blocker such as acebutolol hydrochloride to certain patients has the potential to result in serious adverse health effects. For complete details, please refer to the enclosed acebutolol hydrochloride package insert for contraindications, warnings, precautions, and adverse reactions. Patients who have previously discontinued taking etodolac from the affected lot and have not experienced any side effects should not be concerned.

Pharmacies are hereby instructed to examine their existing inventory of ESI Lederle Etodolac Capsules 300 mg. All remaining inventory of **Lot number 9991052** *(full and partial bottles) must be immediately removed from sale and returned to Pharmacy Solutions, Inc. For return instructions, call Pharmacy Solutions at the number listed in the "Contact Information" section on the next page.*

Other lot numbers are NOT affected by this recall and should NOT be returned by the pharmacy. Additional supplies of ESI Lederle Etodolac Capsules 300 mg are available for reorder from your wholesaler, distribution center, or can be ordered directly from ESI Lederle.

Patient contact and medication disposal:

The affected **Lot number 9991052** *was introduced into commerce on October 18, 1999. Where possible, patients having received capsules from this lot number should be identified and contacted. If you cannot determine the Lot number for product dispensed after October 18, 1999, you should assume it is from the affected lot. Patients should be instructed to contact their physician. Patients should return unused capsules as indicated below.*

ESI Lederle Etodolac Capsules 300 mg can be identified by the following trade dress:

Cap: white gelatin capsule imprinted in red "59911" over "3607"

Body: white gelatin capsule imprinted in red "300"

To arrange a direct patient return to ESI Lederle, patients may call the number listed below in "Contact Information." A mailing kit and postage-paid envelope will be sent directly to the patient. ESI Lederle will reimburse patients directly for all unused Etodolac Capsules 300 mg returned. Patient refunds will be issued via check, prorated at the higher of:

a. *$0.80 per capsule for each capsule returned*
b. *minimum refund amount of $5.00*

The Food and Drug Administration has full knowledge of this recall. If you have any questions or require further information regarding this recall, please contact the appropriate number(s) listed below:

Contact Information:		
Pharmacy Returns:	*Pharmacy Solutions, Inc.*	*800-777-6565*
Patient Returns:	*ESI Lederle*	*800-747-7016*
Product Reorders:	*ESI Lederle Customer Service*	*800-964-6374*
Medical Questions:	*Product Information*	*800-747-7016*
All Other Questions:	*Product Quality Department*	*800-999-9384*

Thank you for your cooperation.

Sincerely,

John Shaughnessy
Vice President, Sales and Marketing - Retail

Enclosures: *Etodolac Capsules full Prescribing Information*
Acebutolol Hydrochloride full Prescribing Information