



URGENT PRODUCT RECALL

September 19, 2005

<u>Product Name/Product size</u>	<u>Product Code</u>	<u>NDC Number</u>
Fluorouracil Injection, USP 500 mg 50mg/mL 10 mL SD Vial	101710	63323-117-10

Dear Customer/Health Professional:

This letter is to notify you that American Pharmaceutical Partners, Inc. is voluntarily recalling the attached list of lots of Fluorouracil Injection, USP.

American Pharmaceutical Partners has decided to take this action as a result of an investigation indicating the vials may contain glass particles.

You are required to return all product from the affected lot in your possession. To implement this recall, please do the following:

1. Examine your stock **immediately** to determine if you have any product from the affected lots.
2. If so, **immediately** discontinue distribution of the affected lots and return all units to American Pharmaceutical Partners, Inc., 600 Supreme Drive, Bensenville, IL 60106 via FedEx Ground using the enclosed return goods label and packing slip. A credit memo will be issued covering the quantity of your return to American Pharmaceutical Partners, Inc.
3. **PLEASE COMPLETE THE ENCLOSED "URGENT PRODUCT RECALL RESPONSE FORM" AND FAX BACK TO US IMMEDIATELY AT 1-847-939-8204 or 1-847 939-8213.**

CONTACT NUMBERS: Please use the following contact phone numbers as appropriate:

<u>Number</u>	<u>Department</u>	<u>Reason to Call</u>
(847) 939-8138	Quality Assurance Department	Information on how to return product
(800) 551-7176	Medical Information	For clinical/technical information

We apologize for any inconvenience this voluntary recall may have caused you.

Yours sincerely,

Margaret Foss
Vice President Quality Assurance and Quality Control
Enclosures



URGENT PRODUCT RECALL

PRODUCT NAME:		<i>Fluorouracil Injection, USP 500 mg 50mg/mL 10 mL SD Vial</i>	
PRODUCT CODE:		101710	
NDC NUMBER:		63323-117-10	
Lot #:	Expiration Date:	First Ship Date:	Last Ship Date:
140493	11/05	9/1/04	10/18/04
140683	12/05	7/27/04	9/14/04
140684	12/05	9/13/04	9/30/04
140943	2/06	9/30/04	10/14/04
140944	2/06	10/14/04	11/09/04
141057	3/06	10/28/04	11/10/04
141058	3/06	11/10/04	11/24/04
141192	4/06	11/24/04	12/9/04
141193	4/06	12/08/04	12/15/04
141328	5/06	12/21/04	1/13/05
141329	5/06	1/5/05	1/20/05
141348	5/06	12/16/04	1/27/05
141349	5/06	1/4/05	2/16/05
141452	6/06	2/14/05	2/28/05
141482	6/06	3/8/05	3/18/05
200117	7/06	3/18/05	4/01/05
200123	7/06	3/30/05	4/13/05
200124	7/06	3/22/05	7/27/05
200143	8/06	4/20/05	5/5/05
200144	8/06	5/5/05	5/12/05
200175	8/06	6/15/05	6/30/05
200176	8/06	5/12/05	6/1/05
200364	9/06	6/24/05	7/19/05
200383	10/06	5/24/05	6/8/05
200384	10/06	6/8/05	7/22/05
200463	10/06	7/20/05	8/4/05
200466	10/06	8/4/05	8/18/05
200467	10/06	8/17/05	8/19/05
200500	11/06	7/29/05	8/19/05



Attn: Urgent Product Recall
PACKING SLIP

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PRODUCT CODE:	101710
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200175	8/06	6/15/05	6/30/05
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200467	10/06	8/17/05	8/19/05
200500	11/06	7/29/05	8/19/05

Hospital (other) _____

Street Address _____

City, State, Zip code _____

Signature _____

PLEASE ENCLOSE THIS FORM WITH YOUR RETURN

URGENT PRODUCT RECALL RESPONSE FORM

Please complete and fax to: **1-847-939-8204 or 1-847-939-8213**

To: American Pharmaceutical Partners, Inc. Attn: Lucille Raimonde

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200500	11/06	7/29/05	8/19/05

- We currently do not have any of the above listed lot numbers on hand.
- We are returning _____ vials.
- We are notifying our direct account customers.

FROM:

Signature: _____

Date: _____