



## URGENT DRUG CORRECTION

September 20, 2005

**Product Name/Product Size**

**Fluorouracil Injection, USP  
50 mg/mL, (500 mg/10 mL Single Dose Vial)**

**Product Code**

**101710**

**NDC Number**

**63323-117-10**

Dear Health Professional:

Recently, American Pharmaceutical Partners, Inc., recalled all lots of Fluorouracil Injection, USP, 50 mg/mL, (500mg/10 mL Single Dose Vial), because there was a potential for invisible glass particles to be present in vials of Fluorouracil Injection, USP, 50 mg/mL, (500mg/10 mL Single Dose Vial). These particles are composed of the glass constituents, silica and aluminum. Only Code 101710 is susceptible to this type of glass breakdown. American Pharmaceutical Partners, Inc.'s other Fluorouracil product codes are manufactured in a different type of glass vial.

To avoid a shortage of this important chemotherapeutic drug, we will provide you with Fluorouracil 10 mL, however, you must use a filter during the preparation of a dose of Fluorouracil Injection, USP, 50 mg/mL, (500mg/10 mL Single Dose Vial), Code 101710. Our studies have demonstrated that by using filters to prepare Fluorouracil Code 101710, you can effectively remove particles from the injection. To ensure that you have access to an appropriate filter, we are temporarily supplying 5 micron filter needles with our Fluorouracil 10 mL vials.

As soon as we have alternate product available, we will discontinue the distribution of these kits. At this time, Pharmacy Bulk Packs (PBPs) are available should you have the ability to use PBPs. The PBPs are not affected by the glass particle problem. The PBPs are available at the same concentration of 50 mg/mL in either 50 or 100 mL sizes (Codes 101751 and 101761, respectively). The 20 mL single dose vial (Code 101720) is not available at this time.

Each 10-count box of Fluorouracil 10 mL will be configured into a kit that includes 10 filter needles and 10 copies of this Drug Correction notice. The kit will be available in several days, in limited quantities. There is no change in the product identifiers, the only change will be in the case pack factor. One shipping case will contain 5 x 10 count kits (50 vials total) instead of the usual 10 x 10 count boxes of vials.

Please notify your staff of the availability of these kits and the following instructions for use:

**Inspect the vial for precipitate** and if any is seen, resolubilize the precipitate according to the instructions in the package insert:

***Note:***

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Although the Fluorouracil solution may discolor slightly during storage, the potency and safety are not adversely affected. If a precipitate occurs due to exposure to low temperatures, resolubilize by heating to 140°F and shaking vigorously; allow to cool to body temperature before using.

After inspecting for precipitation, Fluorouracil Injection, USP Code 101710 must be filtered, whether or not you see precipitate, during dose preparation with the supplied 5 micron BD Filter Needle, Part number 305200:

- 1. Attach the supplied filter needle to a syringe.**
- 2. Withdraw the desired dose from the Fluorouracil Injection, USP 10mL vial.**
- 3. Remove the filter needle prior to performing any subsequent admixture steps or prior to patient administration.**

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

<b><u>Number</u></b>	<b><u>Department</u></b>	<b><u>Reason to Call</u></b>
(847) 939-8138	Quality Assurance Department	Information on Recall or Drug Correction
(800) 551-7176	Medical Information	For clinical/technical information

We apologize for the inconvenience that you may experience and we appreciate your prompt cooperation. The Food and Drug Administration has been notified of this notification.

Yours sincerely,

Margaret Foss  
Vice President Quality Assurance and Quality Control