URGENT DRUG RECALL

January 22, 2013

<table>
<thead>
<tr>
<th>Product Name/Product size</th>
<th>NDC Number</th>
<th>Product Code</th>
<th>Lot Number</th>
<th>Expiration Date</th>
<th>First Ship Date</th>
<th>Last Ship Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irinotecan Hydrochloride Injection, 40 mg/2 mL, (20 mg/mL) 2mL Single Dose Vial</td>
<td>63323-193-02</td>
<td>109302</td>
<td>872CZ00101</td>
<td>12/2013</td>
<td>4/17/2012</td>
<td>11/21/2012</td>
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Dear Customer/Health Professional:

This letter is to notify you that Fresenius Kabi USA, LLC (“Fresenius Kabi”), formerly APP Pharmaceuticals, LLC, is voluntarily recalling the above-mentioned product lot. This recall is being performed to the user level. Fresenius Kabi USA, LLC has decided to take this action due to reports for particulate matter and/or cloudy solution in vials. The preliminary investigation reveals that the particulates were identified as precipitated Irinotecan Hydrochloride. A review of the adverse drug event database failed to identify any adverse drug events involving Irinotecan Hydrochloride Injection Product Code 109302, Lot 872CZ00101.

The administration of crystals, precipitate or other particulates, if present in a parenteral drug poses a potential safety risk to patients. Though there is relatively little data in the literature regarding inadvertent administration of particulate matter in injectable pharmaceuticals, isolated case reports suggest that sequelae of thromboembolism, some life-threatening (such as pulmonary emboli), may occur. There have also been reports in the literature of particulate possibly causing phlebitis, mechanical block of the capillaries or arterioles, activation of platelets, subsequent generation of microthrombi, and emboli. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk. Administration of a crystal or particulate can also lead to formation of granulomas, which represent a protective local inflammatory response to the foreign material and are typically non-serious. Injectable products containing particulate should not be used.

As a precautionary measure, Fresenius Kabi is recalling Irinotecan Hydrochloride Injection, 40 mg/2 mL, (20 mg/mL) 2mL Single Dose Vial, Lot 872CZ00101 in consideration of the potential for safety issues, if precipitated product is administered to patients. Injectable products containing particulate should not be used.

You are required to return all product from the above-mentioned lot that you have 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 lot. If you are a distributor, immediately notify your customers of this recall and direct them to discontinue distributing or dispensing the affected lot. Please have them prepare to return the product to Fresenius Kabi (see enclosed information).

2. If you have the affected lot available, immediately discontinue distributing or dispensing the lot, and return all units to Fresenius Kabi located at 600 Supreme Drive, Bensenville, IL 60106, via FedEx Ground, using a return goods label and packing slip. A FedEx Ground label can be obtained by checking the box and noting your mailing address on the enclosed Urgent Product Recall Response Form. It will be mailed to you upon receiving your request. A credit memo will be issued covering the quantity of your return to Fresenius Kabi.

3. PLEASE COMPLETE THE ENCLOSED “URGENT PRODUCT RECALL RESPONSE FORM” AND FAX IT BACK TO US IMMEDIATELY AT 1-847-413-8574.

CONTACT NUMBERs:

<table>
<thead>
<tr>
<th>Number</th>
<th>Department</th>
<th>Reason to Call</th>
</tr>
</thead>
<tbody>
<tr>
<td>(866) 716-2459</td>
<td>Quality Assurance Department</td>
<td>Information on how to return product</td>
</tr>
<tr>
<td>(800) 551-7176</td>
<td>Vigilance &amp; Medical Affairs</td>
<td>For clinical/technical information</td>
</tr>
</tbody>
</table>

This recall is being made with the knowledge of the US Food and Drug Administration (FDA).

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

Sincerely,

Mitchell L. Ehrlich

Vice President, Quality Assurance
## PACKING SLIP FOR VOLUNTARY RECALL

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Vials (1 each) OR  
Trays/Cartons Returning (Circle One)  

________________________

Hospital (other)  

Street Address  

City, State, Zip code  

Signature  

**PLEASE ENCLOSE THIS FORM WITH YOUR RETURN**
URGENT: DRUG RECALL - Sterile Injectable

January 22, 2013

Please complete and fax to: 1-847-413-8574

To: Fresenius Kabi USA, LLC

Attn: Quality Assurance Department

Product Name/Product size: Irinotecan Hydrochloride Injection, 40 mg/2 mL (20 mg/mL) 2mL Single Dose Vial

NDC Number: 63323-193-02
Product Code: 109302
Lot Number: 872CZ00101
Expiration Date: 12/2013
First Ship Date: 4/17/2012
Last Ship Date: 11/21/2012

1. Examine your inventory immediately to determine if you have any product from the above-mentioned lots.

2. If so, immediately discontinue distribution or dispensing of the affected lots and return all units to Fresenius Kabi USA, LLC located at 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 Fresenius Kabi USA, LLC.

3. PLEASE COMPLETE THIS FORM AND FAX IT BACK TO US IMMEDIATELY AT 1-847-413-8574.

☐ We currently do not have units of the lot numbers on hand.

☐ We are returning ____________ vials  OR  ________ trays/cartons

☐ We are conducting a sub-recall to our direct account customers

4. ☐ Please send us FedEx Ground Shipping Labels to the address below.

FROM: Hospital (other):

Street Address:

City, State, Zip code:

Signature:

From:

FACILITY:
ADDRESS:
CITY, STATE, ZIP:

Signature  ________________________________  Date  ________________

Fresenius Kabi USA, LLC

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