

*Aventis Pharmaceuticals*



March 27, 2001

## **URGENT: VOLUNTARY DRUG RECALL**

**TAXOTERE® (docetaxel) for Injection Concentrate 20-mg NDC# 0075-8001-20**

Dear Wholesaler:

Aventis Pharmaceuticals is initiating a voluntary recall of Taxotere® (docetaxel) for Injection Concentrate 20- mg active and diluent vials. The lot numbers for this recall are: **0P273 (active) which was packaged together with diluent vials with the following lot numbers, 0T446 (diluent) and 0T449 (diluent).**

It has been determined that the Taxotere 20mg vial containing the active ingredient may have been inadvertently labeled as a “diluent” vial. Aventis has received one product complaint relating to this mislabeling. We believe this to be an isolated event, but are nevertheless recalling all affected lots.

Please proceed with the following:

1. Examine your inventory immediately to determine if you have cartons of Taxotere 20-mg vials with the lot numbers listed above.
2. Place any affected inventory on hold. You will receive a business reply card, packing slip and return label in the mail from National Notification Center within 3 – 5 days.
3. On receipt of the returned product, you will be issued a credit for the returned product at list price. You will also receive a \$5 handling fee per unit returned.
4. Taxotere 20mg vials can be immediately reordered through the normal distribution channels.

We are notifying all hospital pharmacies and oncology health care professionals of this recall. However, we ask that you also communicate this information to customers to whom you have sold the listed lots of Taxotere. If you have any questions regarding this recall, please contact our Customer Service Department at 1-800-207-8049. We appreciate your assistance and apologize for the inconvenience . We assure you that Taxotere 20-mg is available to reorder immediately.

Sincerely,

A handwritten signature in black ink, appearing to read "John Leone".

John Leone  
Sr. Vice President & Chief Operating Officer  
US Commercial Operations