

PFIZER TO RECALL TWO ADDITIONAL LOTS OF LIPITOR IN THE U.S.

Pfizer has announced that it intends to recall two additional lots—approximately 38,000 bottles—of Lipitor 40 mg tablets (atorvastatin calcium) distributed in the U.S. The recall stems from two customer reports of an uncharacteristic odor related to the bottles in which these lots of Lipitor were packaged. The bottles were supplied by a third-party bottle manufacturer.

A medical assessment found the risk of health consequences to patients appears to be minimal.

The market action is the result of Pfizer's increased surveillance of odor-related issues after other reports in the industry. This increased surveillance also led to two earlier recalls of Lipitor, implemented in August and October 2010, in response to infrequent complaints of uncharacteristic odor.

The odor is consistent with the presence of 2, 4, 6 tribromoanisole (TBA), which was found at a very low level in a complaint sample bottle during the investigation leading to the first product recall. Research indicates that a major source of TBA appears to be 2, 4, 6-tribromonophenol (TBP), a chemical used as a wood preservative. Although TBP often is applied to pallets used to transport and store a variety of products, Pfizer prohibits the utilization of TBP-treated wood in the shipment of its medicines.

For the U.S. FDA's perspective on TBA and health risk, click on the following web site:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm192869.htm#5>

The company has taken quick action to ensure its product continues to meet the company's high quality and patient safety standards. We have identified the source of the odor, and we are enacting rigorous measures to prevent odor-related issues going forward. The lots that will be recalled were packaged and shipped before these changes went into effect in August of this year.

Pfizer has a very rigorous quality and compliance program that includes a highly sensitive surveillance system, which has enabled the company to quickly detect and respond to the odor-related issue. The company will continue to review all observations to determine if additional action is warranted. The well being of patients who take our medicines is our first priority.

Pfizer does not anticipate a product shortage resulting from the recall.

###