PFIZER TO RECALL ONE ADDITIONAL LOT OF LIPITOR IN THE U.S.
December 2010

Pfizer has announced that it intends to recall one additional lot—approximately 19,000 bottles—of Lipitor 40 mg tablets (atorvastatin calcium) distributed in the U.S. The recall stems from one customer report 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 that 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 three earlier recalls of Lipitor, implemented in August, October and November of 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 lot that will be recalled was packaged and shipped before these changes went into effect in August of this year. As previously reported, product filled in bottles made by the supplier prior to those changes may still be on the market, so it is possible that additional recalls could be necessary.

Pfizer has a very rigorous quality and compliance program that includes a highly sensitive surveillance system, which has enabled Pfizer to quickly detect and respond to the odor-related issue. Our market actions reflect the rigor of our quality control system and a commitment to act rapidly and in the best interest of our customers. The well being of patients who take our medicines is our first priority.

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

# # # #