Indiana State Department of Health
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Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: December 27, 2010

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Pfizer Recall

SUGGESTED ACTION: **Unclassified Recall; Lipitor 40 mg tablets due to an uncharacteristic odor related to the bottles in which these lots of Lipitor were packaged; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled may be distributed in the State of Indiana. The recall stems from one customer report of an uncharacteristic odor related to the bottles in which these lots of Lipitor were packaged. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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Pfizer To Recall One Lot Of Lipitor In The U.S.

Contact:
Pfizer
1-888-LIPITOR

FOR IMMEDIATE RELEASE - December 22, 2010 - Pfizer has announced that it intends to recall one 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[9]

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.

LIPITOR Recall Information

Pfizer recalled specific bottles of LIPITOR (40 mg only) due to a small number of reports of an uncharacteristic odor related to the bottles in which LIPITOR is packaged. A medical assessment has determined that the odor is not likely to cause adverse health consequences in patients taking LIPITOR. There is no need to take any action if you take LIPITOR; please continue to take your medication as prescribed by your doctor. However, if you take LIPITOR 40 mg and experience an uncharacteristic odor associated with your medication, please return the tablets to your pharmacist.

Pfizer is committed to the safety of patients who take our medicines. Pfizer is working closely with the bottle supplier to determine the cause of the odor problem and to rapidly address it. Pfizer responded rapidly to ensure LIPITOR continues to meet the company's high quality standards. We will continue to actively monitor the situation and take any action necessary to ensure patient safety and maintain the quality of our products.

If you have any questions about LIPITOR, please contact your doctor or your pharmacist or call 1-888-LIPITOR.

Common Questions

Why was LIPITOR recalled?
Pfizer has recalled specific "lots" or batches of LIPITOR (40 mg only) due to a small number of reports of an uncharacteristic odor related to the bottles in which the product is packaged. We have

identified the source of the odor, and we are implementing rigorous measures to prevent odor-related issues going forward.

Where can people go for more information about the recall?
If you have any questions about the recall please call 1-888-LIPITOR. If you have specific questions about your medication, you may also call your doctor or pharmacist.

I take LIPITOR. What should I do?
Pfizer recalled only specific bottles of LIPITOR 40 mg due to a small number of reports of an uncharacteristic odor and a medical assessment has determined that the odor is not likely to cause adverse health consequences in patients taking LIPITOR. Medication should always be taken as prescribed by a doctor. If you take LIPITOR 40 mg and experience an uncharacteristic odor associated with your medication, please return the tablets to your pharmacist.

If you take LIPITOR and experience an odd smell or odor, what should you do?
Pfizer recalled only specific bottles of LIPITOR 40 mg due to a small number of reports of an uncharacteristic odor and a medical assessment has determined that the odor is not likely to cause adverse health consequences in patients taking LIPITOR. If you take LIPITOR 40 mg and experience an uncharacteristic odor associated with your medication, please return the tablets to your pharmacist. If you have any concerns, call your doctor or pharmacist or call 1-888-LIPITOR if you need any further information.

Is it still safe to take LIPITOR?
Pfizer has recalled only specific bottles of LIPITOR 40 mg due to a small number of reports of an uncharacteristic odor related to the bottles in which LIPITOR is packaged. A medical assessment has determined the odor is not likely to cause adverse health consequences in patients taking LIPITOR. Pfizer remains confident in the safety and efficacy of LIPITOR.

Will there be a LIPITOR 40 mg shortage as a result of the recall?
Pfizer has taken a number of steps to ensure that there is no shortage of LIPITOR 40 mg as a result of this recall.

Can I have my LIPITOR 40 mg replaced if it has an odd smell or odor?
Pfizer has recalled only specific bottles of LIPITOR 40 mg. Please speak to your pharmacist about replacement policies.

What are the LIPITOR LOT numbers that are recalled?

Lipitor® 40 mg Tablets (atorvastatin calcium) Recall Informaiton	
Lots	**Date of Recall**
0836050	12/17/10
0660060	11/2/10
0682060	11/2/10
0628040	10/13/10
0672040	10/13/10
0673040	10/13/10
0754040	10/13/10

0755040	10/13/10
0763040	10/13/10
0764040	10/13/10
0765040	10/13/10
0788040	10/13/10
0540050	10/13/10
0855020	8/18/10
0819020	8/18/10
0842020	8/18/10
0843020	8/18/10
0854020	8/18/10

LIPITOR (atorvastatin calcium) is a prescription medicine that is used along with a low-fat diet. It lowers the LDL ("bad") cholesterol and triglycerides in your blood. It can raise your HDL ("good") cholesterol as well. LIPITOR can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as age, smoking, high blood pressure, low HDL, or family history of early heart disease.

LIPITOR can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as diabetic eye or kidney problems, smoking, or high blood pressure.

IMPORTANT SAFETY INFORMATION

LIPITOR is not for everyone. It is not for those with liver problems. And it is not for women who are nursing, pregnant or may become pregnant.

If you take LIPITOR, tell your doctor if you feel any new muscle pain or weakness. This could be a sign of rare but serious muscle side effects. Tell your doctor about all medications you take. This may help avoid serious drug interactions. Your doctor should do blood tests to check your liver function before and during treatment and may adjust your dose.

Common side effects are diarrhea, upset stomach, muscle and joint pain, and changes in some blood tests.

When diet and exercise alone are not enough, adding LIPITOR can help lower cholesterol. LIPITOR is one of many cholesterol-lowering treatment options that you and your doctor can consider.