Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

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

DATE: November 30, 2012

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

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

SUBJECT: Ranbaxy Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; 41 affected lots of Atorvastatin Calcium Tablets (10 mg, 20 mg and 40 mg) which is a solid oral dosage form due to the affected lots may contain very small glass particles resembling a fine grain of sand (less than 1 mm in size) ; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled product was distributed in the State of Indiana. The product was distributed in the USA to wholesalers and retailers. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Ranbaxy Issues Voluntary Nationwide Recall of 41 Lots of Atorvastatin Calcium Tablets 10 Mg, 20 Mg and 40 Mg Due to Potential Presence of Foreign Substance

Contact:
Consumer:
1-866-266-7623

Media:
Charles Caprariello
609-720-5615

FOR IMMEDIATE RELEASE - November 28, 2012 - Princeton, NJ -- On November 9, 2012, Ranbaxy Inc. initiated a voluntary recall of 41 affected lots of Atorvastatin Calcium Tablets (10 mg, 20 mg and 40 mg) which is a solid oral dosage form, to the retail level. The Company is taking this voluntary action as a precautionary measure due to the fact that we cannot exclude the possibility that the affected lots may contain very small glass particles resembling a fine grain of sand (less than 1 mm in size). This information is available in Ranbaxy's website at www.ranbaxyusa.com[1]. The recall does not affect or relate to the 80 mg dosage strength of Atorvastatin Calcium Tablets.

The probability of an adverse event due to consumption of this product is unlikely but cannot be ruled out. Because of the size of the particles which may be present in the affected lots it is unlikely to cause a significant safety concern. However, the possibility of adverse experiences arising primarily due to physical irritation cannot be ruled out. As of this date, Ranbaxy has not received any reports of adverse events related to this recall.

The product is used to lower blood cholesterol and is packaged in plastic bottles, as 90 and 500 tablets per bottle. The affected lots of Atorvastatin Calcium Tablets and their respective NDC code, expiration date information are listed below. The product is a white colored tablet and can be identified by the imprint RX12 on 10 mg tablets, RX828 on 20 mg tablets and RX829 on 40 mg tablets. The product was distributed in the USA to wholesalers and retailers.

Ranbaxy has notified its distributors and retailers by e-mail/ FedEx and has arranged for return of the affected lots. Distributors/retailers have stopped further distribution of the affected lots and are in the process of returning any affected product to Ranbaxy.

Consumers with questions regarding this recall can contact Ranbaxy's Customer Coordinator (Inmar) at 1-866-266-7623, Monday to Friday, 8:00 AM to 5:00 PM CST. Consumers should immediately contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online:www.fda.gov/medwatch/report.htm[2]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[3]. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Following is the list of affected lots:

Product	Lot number	Pack Size	NDC #	Expiry Date
ATORVASTATIN	2436144	90's Bottle	63304-827-90	31-Aug-14

Calcium Tablets 10mg x 90				
ATORVASTATIN Calcium Tablets 10mg x 90	2436582	90's Bottle	63304-827-90	31-Aug-14
ATORVASTATIN Calcium Tablets 10mg x 90	2441567	90's Bottle	63304-827-90	31-Aug-14
ATORVASTATIN Calcium Tablets 10mg x 90	2441568	90's Bottle	63304-827-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2436731	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437381	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437940	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437942	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437945	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437947	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437952	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437953	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2437960	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2440676	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg x 90	2440677	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 20mg	2440680	90's Bottle	63304-828-90	31-Aug-14

x 90				
ATORVASTATIN Calcium Tablets 20mg x 90	2440681	90's Bottle	63304-828-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 500	2437956	500's Bottle	63304-829-05	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 500	2437957	500's Bottle	63304-829-05	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 500	2440675	500's Bottle	63304-829-05	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434265	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434266	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434824	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434826	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434827	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434828	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434829	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434830	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2434831	90's Bottle	63304-829-90	31-Jul-14
ATORVASTATIN Calcium Tablets 40mg x 90	2436580	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg	2436725	90's Bottle	63304-829-90	31-Aug-14

x 90				
ATORVASTATIN Calcium Tablets 40mg x 90	2436727	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2436729	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437377	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437380	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437941	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437943	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437944	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437949	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437950	90's Bottle	63304-829-90	31-Aug-14
ATORVASTATIN Calcium Tablets 40mg x 90	2437955	90's Bottle	63304-829-90	31-Aug-14

About Ranbaxy Inc.

Ranbaxy Inc. is a wholly owned subsidiary of Ranbaxy Laboratories Limited (RLL), India's largest pharmaceutical company.

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