



# URGENT: DRUG RECALL

This is a second recall notification letter to notify all customers that the recall has been extended to the **Retail Level** by Dr. Reddy's Laboratories.

February 2, 2017  
Event # 8808

PRODUCT	Product	NDC Number	Lot #	Expiry Date	Size
	Fluconazole 100mg Tablets	0904-6500-61	T-00520	02-2017	10 x 10 Unit Dose
		T-00632	04-2017		
		T-00699	04-2017		
Fluconazole 200mg Tablets	0904-6501-61	T-00519	01-2017	10 x 10 Unit Dose	

Distributed by: Major Pharmaceuticals  
31778 Enterprise Drive  
Livonia, MI 48150 USA

Recalled by: Dr. Reddy's Laboratories Inc.  
107 College Road East  
Princeton, NJ 08540 USA

**REASON**

We have been informed by Dr. Reddy's Laboratories Inc., that they are recalling to the **RETAIL LEVEL**, the products indicated in the table above. The recall was initiated due to "an out-of-specification result obtained for Dissolution (tested with in-house Dissolution method with tighter specifications compared to USP method) during stability testing. Due to the out of specification Dissolution results, the desired therapeutic concentration of the drug may not be achieved at a particular time and thereby it may have effect on the drug action. However, since the product is found to comply with USP method, it is unlikely to have an impact on the efficacy of the Fluconazole tablets and the recall is being done as an abundant precaution."

**ACTIONS TO BE TAKEN**

1. Stop distributing and quarantine the affected lots.
2. Please carry out a physical count and record this data on the Business Reply Form/Packing Slip which is included with this letter.
3. Fax the Business Reply Form **even if you do not have the recalled product to 1-844-861-6232 or email to [harvarddrug8808@stericycle.com](mailto:harvarddrug8808@stericycle.com).**
4. Return the recalled product and the Packing Slip using the prepaid UPS Return Service shipping label to:  
  
Stericycle, Inc.  
2670 Executive Dr., Suite A  
Indianapolis, IN 46241  
Attn: Event # 8808
5. If you have further distributed the product, please notify your **Wholesale / Retail** customers immediately and have them return the product back to you.

**OTHER INFORMATION**

This recall is being carried out to the **RETAIL LEVEL** and is only for the specific product / lots listed above. No other lots, packages, or formulations are being recalled.

**This product was shipped from our Indianapolis warehouse between 07/14/15 and 01/08/16.**

For questions regarding returns, please contact Stericycle at 1-844-861-6220. For medical-related questions, please contact your physician. For all other questions, please contact Major Pharmaceuticals at 1-800-616-2471.

**To ensure proper credit, please return recalled merchandise before May 2, 2017.** Any other product sent in addition or in lieu of recalled product will be destroyed, without issuance of credit to your account.

This recall is being made with the knowledge of the FDA. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.