URGENT: DRUG RECALL

July 19, 2018

PRODUCT

Product	NDC Number	Size	Lot Number	Expiry Date
Valsartan 80mg Tablets, USP	0904-6594-61	10 x 10 Unit Dose	T-01270	07-2018
			T-01466	07-2018
			T-01500	02-2019
			T-01596	02-2019
			T-01625	02-2019
			T-01712	02-2019
			T-01795	05-2019
			T-01807	05-2019
Valsartan 160mg Tablets, USP	0904-6595-61	10 x 10 Unit Dose	T-01269	07-2018
			T-01524	02-2019
			T-01646	05-2019
			T-01668	05-2019
			T-01788	05-2019

Distributed by: Major Pharmaceuticals
17177 N. Laurel Park Dr., Suite 233
Livonia, MI 48152

REASON

We have been informed by the Food and Drug Administration the above products manufactured by Teva and labeled as Major Pharmaceuticals, may contain N-nitrosodimethylamine (NDMA), a probable carcinogen.

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 1-877-766-7471 or email to** harvarddrug5959@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 # 5959
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 products / lots listed above. No other lots, packages, or formulations are being recalled.

These products were shipped from our Indianapolis warehouse between March 15, 2017 and July 11, 2018.

For questions regarding returns, please contact Stericycle at 1-877-448-5317. For medical-related questions, please contact Teva Pharmaceuticals at 1-888-838-2872, option 3, then option 4 or your physician. For all other questions, please contact Major Pharmaceuticals at 1-800-616-2471.

To ensure proper credit, please return recalled merchandise before October 20, 2018. 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.