SECOND NOTICE -- URGENT DRUG RECALL

Date August 23, 2018

Product Name	Description	NDC	Batch/Lot
Amlodipine/Valsartan/ HCTZ Tablets	10mg/320mg/25mg, 10mg/160mg/25mg, 10mg/160mg/12.5mg, 5mg/160mg/12.5mg & 5mg/160mg/25mg	**13668-325-30** **13668-328-30** **13668-327-30** **13668-326-30** **13668-329-30**	See Attached List
Amlodipine/Valsartan Tablets	5 mg/160 mg 10 mg/160 mg 10 mg/320 mg 5 mg/320 mg	**13668-207-30** **13668-206-30** **13668-204-30** **13668-205-30**	
Valsartan Tablets	80 mg 160 mg 320 mg	**13668-068-90** **13668-069-90** **13668-070-90**	

Dear Customer,

On Friday August 17, 2018 Torrent Pharmaceuticals Limited initiated a voluntary recall to the consumer level of Valsartan/Amlodipine/HCTZ Tablets. On Aug 20 and 21, 2018 we expanded the number of impacted batches for that product and added Amlodipine/Valsartan tablets and Valsartan tablets to the ongoing recall. Today we are expanding the number of impacted batches for these 3 products. The list below represents ALL LOTS of Torrent product that is within expiry. Our records indicate that you have purchased product from the subject batch/lot. This recall is being conducted with the knowledge of the Food and Drug Administration.

This recall is due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals. The impurity detected in the API is N-nitrosodimethylamine (NDMA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification.

Torrent Pharmaceuticals Limited requests that you immediately take the following actions:

1. Immediately examine your inventory, quarantine product subject to the recall and Stop distribution of the lot(s) identified below. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

2. Please complete the enclosed Business Response Form indicating either:
    a. You have examined your inventory and have none of the recalled product in Stock or,
    b. Upon examining your inventory you have found the effected recall product which will be quarantined. In the event you have Recall product, please return to Qualanex, LLC., using the Postage Paid Product Return label that will be provided and mail to the following:

13668-00162-01027094
Smith Drug Company
PO Box 1779
Spartanburg, SC 29301

Qualanex, LLC.
1410 Harris Road
Libertyville, IL 60048

3. Please return the enclosed Business Response Form via fax to 1-847-737-3719 or email to Recall@qualanex.com .

This action applies only to the products and lots addressed in this notification. Only product from these batch/lot will be accepted under the terms of this recall.

- If you have any medical questions regarding this recall, please contact Torrent Pharma Inc. at 1-800-912-9561 (8:00 am – 5:00 pm Eastern Time).
- If you have any general questions regarding the return of this product please contact Qualanex at 1-888-424-4340 or
  1-800-505-9291 (8:00 am-5:30 pm Eastern Time).

We regret any inconvenience and appreciate your immediate cooperation.

Bernadette Attinger
Senior Director, Regulatory Affairs

NDC	Product Description	Lot/Batch	Expiration Date
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D025	Nov-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D026	Nov-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2E001	Jan-2020
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2E002	Jan-2020
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2E003	Jan-2020
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2E004	Jan-2020
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2E005	Jan-2020
NDC 13668-328-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/25mg, 30 Tablets	BBX9D004	Nov-2019
NDC 13668-328-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/25mg, 30 Tablets	BBX9E001	Jan-2020
NDC 13668-326-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/12.5mg, 30 Tablets	BBY1E001	Dec-2019

13668-00162-01027094
Smith Drug Company
PO Box 1779
Spartanburg, SC 29301

NDC	Product Description	Lot/Batch	Expiration Date
NDC 13668-326-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/12.5mg, 30 Tablets	BBY1E003	Mar-2020
NDC 13668-327-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/12.5mg, 30 Tablets	BBY2E001	Mar-2020
NDC 13668-329-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/25mg, 30 Tablets	BBY4D004	Nov-2019
NDC 13668-329-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/25mg, 30 Tablets	BBY4E001	Jan-2020
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D003	Mar-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D004	Mar-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D005	Mar-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D006	Mar-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D007	Mar-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D008	Mar-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D015	Oct-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D016	Oct-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D017	Oct-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D018	Oct-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D019	Oct-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D020	Oct-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D021	Oct-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D022	Oct-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D023	Oct-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D024	Nov-2019
NDC 13668-328-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/25mg, 30 Tablets	BBX9D001	Feb-2019

13668-00162-01027094
Smith Drug Company
PO Box 1779
Spartanburg, SC 29301

NDC	Product Description	Lot/Batch	Expiration Date
NDC 13668-326-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/12.5mg, 30 Tablets	BBY1C002	Sep-2018
NDC 13668-326-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/12.5mg, 30 Tablets	BBY1E002	Mar-2020
NDC 13668-327-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/12.5mg, 30 Tablets	BBY2D001	Feb-2019
NDC 13668-327-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/12.5mg, 30 Tablets	BBY2D002	Nov-2019
NDC 13668-207-30	Amlodipine and Valsartan Tablets 5 mg/160 mg, USP, 30 Tablets	BV53D004	Oct-2019
NDC 13668-206-30	Amlodipine and Valsartan Tablets 10 mg/160 mg, USP, 30 Tablets	BV65D002	Oct-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D013	Oct-2019
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84D010	Oct-2019
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84E001	Dec-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D001	Dec-2018
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D002	Dec-2018
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D009	Mar-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D010	Apr-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D011	Apr-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D012	May-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D013	May-2019
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2D014	Aug-2019
NDC 13668-328-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/25mg, 30 Tablets	BBX9D002	Mar-2019
NDC 13668-328-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/160mg/25mg, 30 Tablets	BBX9D003	Jul-2019
NDC 13668-326-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/12.5mg, 30 Tablets	BBY1D001	May-2019
NDC 13668-329-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/25mg, 30 Tablets	BBY4D001	Apr-2019

13668-00162-01027094
Smith Drug Company
PO Box 1779
Spartanburg, SC 29301

NDC	Product Description	Lot/Batch	Expiration Date
NDC 13668-329-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/25mg, 30 Tablets	BBY4D002	Apr-2019
NDC 13668-329-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 5mg/160mg/25mg, 30 Tablets	BBY4D003	Jun-2019
NDC 13668-068-90	Valsartan Tablets, USP, 80 mg, 90 Tablets	BV46C007	Sep-2018
NDC 13668-068-90	Valsartan Tablets, USP, 80 mg, 90 Tablets	BV46C008	Oct-2018
NDC 13668-068-90	Valsartan Tablets, USP, 80 mg, 90 Tablets	BV46C009	Oct-2018
NDC 13668-068-90	Valsartan Tablets, USP, 80 mg, 90 Tablets	BV46C010	Oct-2018
NDC 13668-068-90	Valsartan Tablets, USP, 80 mg, 90 Tablets	BV46C011	Nov-2018
NDC 13668-068-90	Valsartan Tablets, USP, 80 mg, 90 Tablets	BV46C012	Nov-2018
NDC 13668-069-90	Valsartan Tablets, USP, 160 mg, 90 Tablets	BV47C005	Sep-2018
NDC 13668-069-90	Valsartan Tablets, USP, 160 mg, 90 Tablets	BV47C006	Sep-2018
NDC 13668-069-90	Valsartan Tablets, USP, 160 mg, 90 Tablets	BV47D001	Dec-2018
NDC 13668-070-90	Valsartan Tablets, USP, 320 mg, 90 Tablets	BV48D001	Dec-2018
NDC 13668-070-90	Valsartan Tablets, USP, 320 mg, 90 Tablets	BV48D002	Dec-2018
NDC 13668-207-30	Amlodipine and Valsartan Tablets 5 mg/160 mg, USP, 30 Tablets	BV53C006	Nov-2018
NDC 13668-207-30	Amlodipine and Valsartan Tablets 5 mg/160 mg, USP, 30 Tablets	BV53D001	Feb-2019
NDC 13668-207-30	Amlodipine and Valsartan Tablets 5 mg/160 mg, USP, 30 Tablets	BV53D002	Feb-2019
NDC 13668-207-30	Amlodipine and Valsartan Tablets 5 mg/160 mg, USP, 30 Tablets	BV53D003	Sep-2019
NDC 13668-206-30	Amlodipine and Valsartan Tablets 10 mg/160 mg, USP, 30 Tablets	BV65C002	Sep-2018
NDC 13668-206-30	Amlodipine and Valsartan Tablets 10 mg/160 mg, USP, 30 Tablets	BV65C003	Oct-2018
NDC 13668-206-30	Amlodipine and Valsartan Tablets 10 mg/160 mg, USP, 30 Tablets	BV65C004	Nov-2018
NDC 13668-206-30	Amlodipine and Valsartan Tablets 10 mg/160 mg, USP, 30 Tablets	BV65D001	Aug-2019

13668-00162-01027094
Smith Drug Company
PO Box 1779
Spartanburg, SC 29301

NDC	Product Description	Lot/Batch	Expiration Date
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77C011	Oct-2018
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D001	Feb-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D002	Feb-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D003	Feb-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D004	Feb-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D005	Feb-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D006	Feb-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D007	Feb-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D008	May-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D009	Aug-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D010	Sep-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D011	Sep-2019
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77D012	Sep-2019
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84C011	Oct-2018
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84D001	Jan-2019
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84D002	Jan-2019
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84D005	Feb-2019
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84D006	Feb-2019
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84D007	Feb-2019
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84D008	May-2019
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84D009	May-2019

13668-00162-01027094
Smith Drug Company
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Spartanburg, SC 29301

NDC	Product Description	Lot/Batch	Expiration Date
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77C009	Aug-2018
NDC 13668-204-30	Amlodipine and Valsartan Tablets 10 mg/320 mg, USP, 30 Tablets	BV77C010	Aug-2018
NDC 13668-207-30	Amlodipine and Valsartan Tablets 5 mg/160 mg, USP, 30 Tablets	BV53C004	Aug-2018
NDC 13668-207-30	Amlodipine and Valsartan Tablets 5 mg/160 mg, USP, 30 Tablets	BV53C005	Aug-2018
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84C006	Aug-2018
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84C007	Aug-2018
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84C008	Aug-2018
NDC 13668-205-30	Amlodipine and Valsartan Tablets 5 mg/320 mg, USP, 30 Tablets	BV84C009	Aug-2018
NDC 13668-325-30	Amlodipine, Valsartan and Hydrochlorothiazide Tablets, USP 10mg/320mg/25mg, 30 Tablets	BBX2C007	Aug-2018
NDC 13668-069-90	Valsartan Tablets, USP, 160 mg, 90 Tablets	BV47C003	Aug-2018
NDC 13668-069-90	Valsartan Tablets, USP, 160 mg, 90 Tablets	BV47C004	Aug-2018
NDC 13668-068-90	Valsartan Tablets, USP, 80 mg, 90 Tablets	BV46C003	Aug-2018
NDC 13668-068-90	Valsartan Tablets, USP, 80 mg, 90 Tablets	BV46C006	Aug-2018

13668-00162-01027094
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SECOND NOTICE

UPDATED AUG 23, 2018: URGENT DRUG RECALL BUSINESS RESPONSE FORM

Product Name	Description	NDC	Batch/Lot
Amlodipine/Valsartan/ HCTZ Tablets	10mg/320mg/25mg, 10mg/160mg/25mg, 10mg/160mg/12.5mg, 5mg/160mg/12.5mg & 5mg/160mg/25mg	13668-325-30 13668-328-30 13668-327-30 13668-326-30 13668-329-30	All lots within expiration
Amlodipine/Valsartan Tablets	5 mg/160 mg 10 mg/160 mg 10 mg/320 mg 5 mg/320 mg	13668-207-30 13668-206-30 13668-204-30 13668-205-30	All lots within expiration
Valsartan Tablets	80 mg 160 mg 320 mg	13668-068-90 13668-069-90 13668-070-90	All lots within expiration

Please fill out and either fax to (847) 737-3719 or email to Recall@qualanex.com.

NDC: _____ Lot: _____

Quantity Being Returned Full/Sealed Bottles Partial Bottles Tablet Count of Partial Bottles

_____ _____ _____

NDC: _____ Lot: _____

Quantity Being Returned Full/Sealed Bottles Partial Bottles Tablet Count of Partial Bottles

_____ _____ _____

NDC: _____ Lot: _____

Quantity Being Returned Full/Sealed Bottles Partial Bottles Tablet Count of Partial Bottles

_____ _____ _____

NDC: _____ Lot: _____

Quantity Being Returned Full/Sealed Bottles Partial Bottles Tablet Count of Partial Bottles

_____ _____ _____

We have examined our inventories and have none of the above recalled product in stock: (initials) ____

Completed by: (Please Print)

Name/Title:_____

E-Mail: _____

Company Name:_____

Address:_____

City, State, Zip:_____

DEA Number: _____

Date: _____

Phone: _____

Wholesaler:_____

Wholesaler AccT#_____

DEA Number: _____

Signature:_____

13668-00162-01027094
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Spartanburg, SC 29301