Boehringer Ingelheim

Urgent: Voluntary Drug Recall

October 22, 2018

Dear Supply Chain Partner:

Boehringer Ingelheim Pharmaceuticals, Inc. (BI) is voluntarily initiating a drug recall of one (1) lot of CATAPRES® Tablets at the **wholesale/distributor and retail pharmacy levels**. This recall is being conducted with the knowledge of the Food and Drug Administration.

Product	NDC No.	Lot No.	Exp. Date	Ship Dates to Wholesalers
CATAPRES® Tablets (clonidine hydrochloride, USP) 0.2 mg 100 Tablets per Bottle	0597-0007-01	757739	SEP 2020	01/04/2018 – 09/24/2018

Reason for Recall:
This recall is being conducted, for the subject lot, due to out of specification (OOS) results that were obtained during routine stability testing for the dissolution test. All other testing parameters for this lot are within specification. There have been no Adverse Events (AE) reported in conjunction with the affected lot. Based on BI's understanding of this product and the available information, the likelihood of adverse outcomes is remote. Based on the medical evaluation of the available data, the use of CATAPRES® 0.2 mg tablets, affected by the OOS, is considered not likely to cause adverse health consequences.

Important Basic Information:
This recall is limited to the one lot number listed above and extends to the wholesale and retail pharmacy levels only. **No other Boehringer Ingelheim products or lots are impacted by this recall.**

Action Required by the Wholesaler/Distributor:

- **Stop distributing this lot immediately and segregate any product remaining in your inventory for return.**
- Immediately copy and forward this "Dear Supply Chain Partner" letter to any of your direct retail or distributor consignees to whom the affected product lot was distributed.
- Once you have notified your retail and distributor consignees, please complete the enclosed Business Reply Card (BRC), indicating that you have contacted your consignees, and immediately return the BRC to FedEx Supply Chain.
- Please do not include any other products/lots in this return shipment. Return of the product for this recall must be separate from all other returns and **returned only to FedEx Supply Chain, 6101 North 64th Street, Milwaukee, WI 53218.**

Action Required by the Retailer/Pharmacy:

- **Stop dispensing this lot immediately and segregate any product remaining in your inventory for return.**
- Contact FedEx Supply Chain (GENCO Pharmaceutical Services) at 866-312-8042 to request a shipping label and return kit, to use for return shipment and to discuss any reimbursement questions.
- Once you receive the shipping label and return kit, immediately ship to FedEx Supply Chain. Do not include any other products/lots in this return shipment. Return of the product for this recall must be separate from all other returns and **returned only to FedEx Supply Chain, 6101 North 64th Street, Milwaukee, WI 53218.**

Boehringer Ingelheim Pharmaceuticals, Inc. will issue a credit for all returned goods associated with this recall notice, as well as the costs of the recall as described in the HDA guidance.

For information regarding this recall, please reference the following telephone numbers:

- For information regarding the recall process, call FedEx Supply Chain (GENCO) at 866-312-8042.
- For medical or technical product information or to report a technical product complaint, call 800-542-6257.

We are diligently working to resolve this issue as quickly as possible. Boehringer Ingelheim Pharmaceuticals, Inc. is committed to supplying our customers with quality products. We apologize for this inconvenience and thank you for your time and continued support. Your cooperation and compliance with the requests in this letter are appreciated.

Sincerely,

Elizabeth Trowbridge

Elizabeth Trowbridge
Director, Quality Assurance and Compliance