VIATRIS™

1000 Mylan Boulevard
Canonsburg, PA 15317

March 23, 2022

RE: Recall of Quinapril and Hydrochlorothiazide Tablets, 20/25mg, Quinapril HCl/Hydrochlorothiazide Tablets, 20/12.5mg, and Quinapril HCl/Hydrochlorothiazide Tablets, 20/25mg

Dear Greenstone Customer:

Pfizer is conducting a recall of the below five lots of Quinapril and Hydrochlorothiazide Tablets and Quinapril HCl/Hydrochlorothiazide Tablets, which Greenstone distributed between November 2019 and March 2022.

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
59762-5225-9	FE3714	02/2023	20/25 mg	1 x 90 count bottle
59762-0220-1	DN6931	03/2023	20/12.5 mg	1 x 90 count bottle
59762-0220-1	ED3904	03/2023	20/12.5 mg	1 x 90 count bottle
59762-0220-1	ED3905	03/2023	20/12.5 mg	1 x 90 count bottle
59762-0223-1	DP3414	02/2023	20/25 mg	1 x 90 count bottle

Please review the attached recall letter from Pfizer in its entirety and follow the steps outlined in the letter.

Please direct any questions regarding this recall to Pfizer at the contact numbers provided within the recall letter. If you have any questions regarding Greenstone product availability, please contact Greenstone Customer Service at 800-447-3360 (Mon.-Fri. 8 am-5:30 pm ET). We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this action may cause.

Sincerely,

URGENT: DRUG RECALL

March 23, 2022

Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 10/12.5 mg
Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 20/12.5 mg
Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 20/25 mg

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0071-3112-23	FG5379	08/2024	10/12.5 mg	1 x 90 count bottle
0071-0222-23	EA6686	04/2022	10/12.5 mg	1 x 90 count bottle
0071-5212-23	FG5381	08/2024	20/12.5 mg	1 x 90 count bottle
0071-0220-23	EA6665	04/2022	20/12.5 mg	1 x 90 count bottle
0071-0220-23	CN0640	04/2022	20/12.5 mg	1 x 90 count bottle
0071-0223-23	ET6974	02/2023	20/25 mg	1 x 90 count bottle

quinapril and hydrochlorothiazide tablets, 20/25 mg
quinapril HCl/hydrochlorothiazide tablets, 20/12.5 mg
quinapril HCl/hydrochlorothiazide tablets, 20/25 mg

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59762-0220-1	ED3905	03/2023	20/12.5 mg	1 x 90 count bottle
59762-0223-1	DP3414	02/2023	20/25 mg	1 x 90 count bottle

Dear Customer:

Pfizer Inc. is voluntarily recalling the above referenced lots of **Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, quinapril and hydrochlorothiazide tablets** and **quinapril HCl/hydrochlorothiazide tablets.**

Pfizer initiated this recall due to the presence of n-nitroso-quinapril above the Acceptable Daily Intake (ADI) level. Pfizer conducted a toxicological evaluation to establish an ADI, which incorporated numerous conservative assumptions. Pfizer also conducted a Product Assessment, including an evaluation of safety surveillance data. Based on Pfizer's assessments, the benefit/risk of quinapril and hydrochlorothiazide remains positive based on currently available data. Although a potential excess lifetime cancer risk from n-nitroso-quinapril may exist, it is considered to be low based on currently available data.

To date, Pfizer is not aware of reports of adverse events assessed to be related to this recall.

FEDERAL REGULATION 21 CFR 7.49 (d) RESPONSIBILITY OF RECIPIENT STATES: "CONSIGNEES THAT RECEIVE A RECALL COMMUNICATION SHOULD IMMEDIATELY CARRY OUT THE INSTRUCTIONS SET FORTH BY THE RECALLING FIRM ..." PFIZER RECOMMENDS THAT YOU RESPOND TO THIS RECALL EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED BUSINESS REPLY FORM (BRF) AND RETURN IT, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS. If you have any questions about responding to this letter, please contact Sedgwick at 888-843-0247 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above referenced lots of **Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, quinapril and hydrochlorothiazide tablets** and **quinapril HCl/hydrochlorothiazide tablets** is being conducted to the **Consumer/User level.**

Instructions for Wholesalers, Retailers, Hospitals and Health Care Providers:
Our records indicate that you received shipment of one or more of the affected product lots, which were distributed between **November 2019 to March 2022**. Please check your stock immediately against the tables above. If you have any of the affected lots in your inventory, please stop distribution and quarantine the product immediately. Promptly return the product to Sedgwick; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 3885 using the enclosed pre-paid UPS label. **All returns are requested to be completed within six months of this notice date.** If you received this notification without the prepaid UPS label and BRF, require additional shipping labels, or have questions regarding the return procedure, please contact Sedgwick at 888-843-0247.

If you have further distributed the recalled product, please notify any accounts and/or additional locations which may have received the recalled product. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request they immediately cease distribution and quarantine the affected product. Promptly contact Sedgwick at 888-843-0247 (Mon.-Fri. 8 am-5 pm ET) to obtain pre-paid shipping labels to initiate the return process.

If the product has been dispensed to patients, please notify these customers regarding this recall.

Reimbursement for the returned product will be made by credit memorandum. Please contact Pfizer Customer Service at 800-533-4535 (Mon.-Fri. 8 am-5:30 pm ET) or your Pfizer representative regarding product availability and questions regarding this market action.

Instructions for Patients:
Patients who are taking this product should consult with their health care provider about alternative treatment options. Patients with the product should contact Sedgwick at 888-843-0247, (Mon.-Fri. 8:00 am – 5:00 pm ET) for instructions on how to return their product and obtain reimbursement for their cost.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this action may cause you.

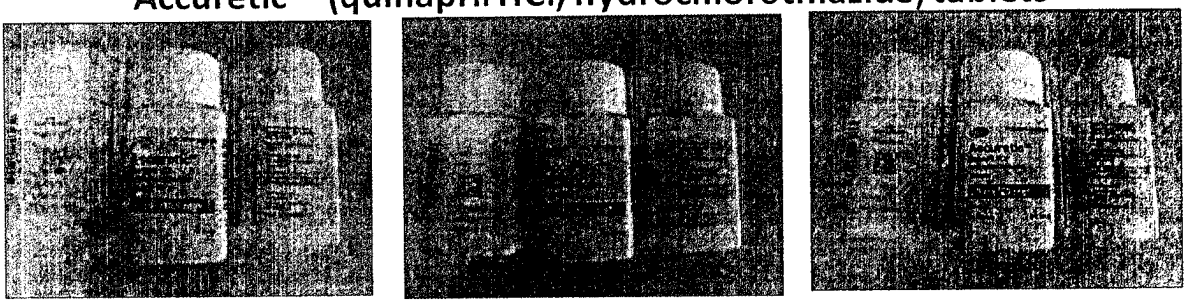
If you have any questions regarding this recall, please call the appropriate contact center below.

Contact Center	Contact Information	Area of Support
Pfizer Medical Information	800-438-1985, option 3 (Mon.-Fri. 8 am-9 pm ET) www.pfizermedinfo.com	For medical questions regarding the product
Pfizer Drug Safety	800-438-1985, option 1 (24 hours a day; 7 days a week)	To report adverse events and product complaints
Sedgwick	888-843-0247 (Mon.-Fri. 8 am-5 pm ET)	For product returns and reimbursement questions

Sincerely,
Lou Dallago

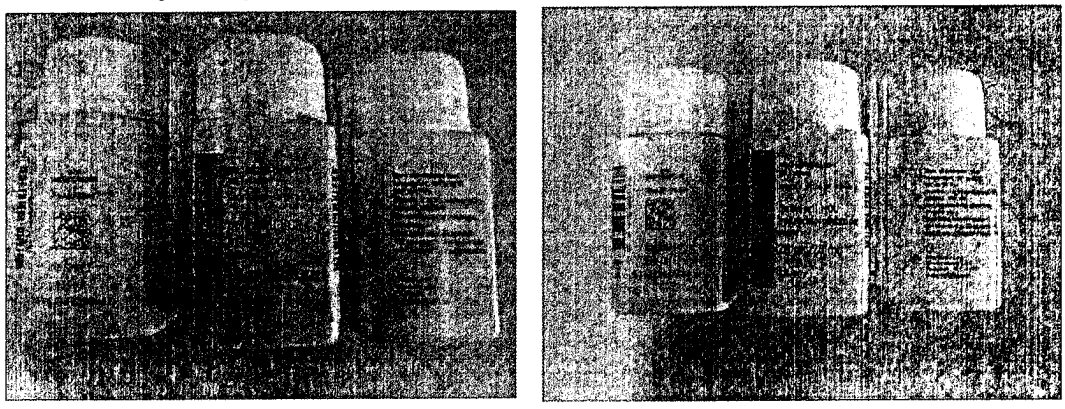
Vice President U.S. Trade Group

Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets



quinapril and hydrochlorothiazide tablets

quinapril HCl/hydrochlorothiazide tablets



PLEASE COMPLETE THIS FORM AND RETURN VIA FAX TO 1-877-546-0124 OR EMAIL TO PFIZER3885@SEDGWICK.COM
EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. MAKE A COPY OF THIS FORM TO INCLUDE WITH YOUR PRODUCT RETURN.

BUSINESS REPLY FORM/PACKING SLIP

Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 10/12.5 mg,
Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 20/12.5 mg
Accuretic™ (quinapril HCl/hydrochlorothiazide) tablets, 20/25 mg

NDC #	Lot #	Expiration Date	SEALED BOTTLES	UNSEALED BOTTLES	# OF TABLETS IN UNSEALED BOTTLES
0071-3112-23	FG5379	08/2024			
0071-0222-23	EA6686	04/2022			
0071-5212-23	FG5381	08/2024			
0071-0220-23	EA6665	04/2022			
0071-0220-23	CN0640	04/2022			
0071-0223-23	ET6974	02/2023			

quinapril and hydrochlorothiazide tablets, 20/25 mg
quinapril HCl/hydrochlorothiazide tablets, 20/12.5 mg
quinapril HCl/hydrochlorothiazide tablets, 20/25 mg

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59762-0220-1	ED3904	03/2023			
59762-0220-1	ED3905	03/2023			
59762-0223-1	DP3414	02/2023			

Your timely response to this notification is requested. Please complete and fax this Business Reply Form/Packing Slip within five (5) business days **even if you do not have the recalled product.** Thank you.

- ☐ We have read and understand the urgent drug recall information.
- ☐ We have/will further notify our accounts who may have received the affected product lots, to the Consumer/User Level.
- ☐ We do not have any of the affected product lots on hand.

To report any adverse events or product complaints, please contact Pfizer Safety at 1-800-438-1985, option 1.

Signature: _____ Title: _____

Name: _____ Phone: _____

Direct Acct #: _____ Indirect Acct #: _____

Customer Debit Memo #: _____

Wholesaler DEA #: _____

DEA #: _____

The below shipping label is not intended for multiple shipments. Please DO NOT duplicate or re-distribute.

Ship To: SEDGWICK
2670 EXECUTIVE DRIVE SUITE A
INDIANAPOLIS IN 46241

RS
ID: 72867839
Event: 3885
Seq.# 68

IN 462 8-01

UPS GROUND
TRACKING: 1Z E38 010 90 1920 6736

PACKING INSTRUCTIONS:

1. Fill out this packing slip and photocopy it for your records. Return this original packing slip with your product shipment.

2. Affix prepaid UPS RS shipping label to shipping container (if reusing a shipping container, remove or mark out all labels, stickers, hazmat and ORM markings). Give directly to any UPS driver or deliver to UPS. (Do not enter this shipment in a UPS log book or apply any other UPS shipping label or bar code.)

3. Keep this for your records. All follow-up will be based on this shipping information.

TRACKING: 1Z E38 010 90 1920 6736

ID 72867839 Event 3885
PHARMACY BUYING ASSOCIATON

GIY-04-12