

URGENT: DRUG RECALL

**CARVEDILOL TABLETS USP 3.125mg, 12.5mg, and 25mg
100s and 500s Container pack (Tablets)
(NDC 68462-162-01, 68462-162-05, 68462-164-05, 68462-165-05)
Glenmark**

August 7, 2025

Dear Pharmacy, Wholesale and Retail Customer:

This is to inform you that Glenmark is initiating a voluntary recall to the Retail level involving the following prescription product:

Carvedilol Tablets USP 3.125mg (100's Tablets)

Sr. No.	NDC Code	Batch Number	Pack Size	Expiry Date
1	68462-162-01	19242272	100's Tablets in Container	May-26

Carvedilol Tablets USP 3.125mg (500's Tablets)

Sr. No.	NDC Code	Batch Number	Pack Size	Expiry Date
1	68462-162-05	19242274	500's Tablets in Container	May-26
2	68462-162-05	19242275	500's Tablets in Container	May-26
3	68462-162-05	19242272	500's Tablets in Container	May-26

Carvedilol Tablets USP 12.5mg (500's Tablets)

Sr. No.	NDC Code	Batch Number	Pack Size	Expiry Date
1	68462-164-05	19243202	500's Tablets in Container	Jul-26

Carvedilol Tablets USP 25mg (500's Tablets)

Sr. No.	NDC Code	Batch Number	Pack Size	Expiry Date
1	68462-165-05	19243104	500's Tablets in Container	Jul-26

The recall to the retail level of the above-identified Carvedilol Tablets USP 3.125mg, 12.5mg, and 25mg batches have been initiated due to the presence of a nitrosamine, 'N-Nitroso Carvedilol I' Impurity above the current Acceptable Intake Level. To date, Glenmark has not received any reports of adverse events related to this recall.

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products, and vegetables. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time, but there is no immediate risk to patients taking the medication and the probability of serious adverse health consequences is remote.

Please see the details of product batches listed in the above table and refer to the enclosed product labels for ease in identifying the product.

Please examine your inventory and if you have any inventory available for the batches specified in the above table, you should quarantine such product immediately and not dispense any further product from these lots. Glenmark Pharmaceuticals Inc., USA initiated shipment of this product on 08/28/2024.

In addition, if you are a wholesaler/ distributor, who has further distributed this product, please identify those retail customers and notify them at once of this Product recall. Your notification to your retail customers may be enhanced by including a copy of this recall notification letter. Again, this recall should be carried out to the retail level only. Because this is not a consumer-level recall, notice to the consumer level is not required.

Glenmark is requesting the batches specified in the above table to be returned to Inmar Rx Solutions (address below) using the Postage Paid Product Return label that was provided in your Recall Return Packet.

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 817-868-5362 or email to Rxrecalls@Inmar.com.

If you have any questions regarding your recall return please contact Inmar at **855-709-6717**

Inmar office hours are Monday through Friday, from 9 am to 5 pm EST.

This recall is being made with the knowledge of the Food and Drug Administration.

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

thomas.callaghan@glenmarkpharma.com
Digitally signed by
thomas.callaghan@glenmarkpharma.com
Date: 2025.08.07 09:30:53 -04'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

Recall Return Response Form

Product labels:

Carvedilol Tablets USP 3.125mg (100 Tablets in Container)

JAR SIZE : 40 CC
SAME SIZE ARTWORK
LABEL SIZE : 105 mm x 30 mm

NDC 68462-162-01

**Carvedilol
Tablets, USP**

3.125 mg

glenmark

Rx Only 100 Tablets

Each tablet contains carvedilol USP, 3.125 mg.
Product meets USP Dissolution Test 2
Usual Dosage: See accompanying prescribing information.
Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container.
Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.
Manufactured by:
Glenmark Pharmaceuticals Ltd.
Colvale-Bardez, Goa 403513, India
GO/DRUGS/648
Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
09/19

PE444770919-1

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

JAR/US-RED AREA
32 mm x 30 mm

Carvedilol Tablets USP 3.125mg (500 Tablets in Container)

JAR SIZE : 40 CC
SAME SIZE ARTWORK
LABEL SIZE : 105 mm x 30 mm

NDC 68462-162-05

**Carvedilol
Tablets, USP**

3.125 mg

glenmark

Rx Only 500 Tablets

Each tablet contains carvedilol USP, 3.125 mg.
Product meets USP Dissolution Test 2
Usual Dosage: See accompanying prescribing information.
Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container.
Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.
Manufactured by:
Glenmark Pharmaceuticals Ltd.
Colvale-Bardez, Goa 403513, India
GO/DRUGS/648
Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
09/19

PE444770919-1

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

JAR/US-RED AREA
32 mm x 30 mm

Carvedilol Tablets USP 12.5mg (500 Tablets in Container)

JAR SIZE : 150 CC
SAME SIZE ARTWORK
LABEL SIZE : 130 mm x 50 mm

NDC 68462-164-05 Carvedilol Tablets, USP 12.5 mg glenmark	
Rx Only	500 Tablets

Each tablet contains carvedilol USP, 12.5 mg.
Product meets USP Dissolution Test 2
Usual Dosage: See accompanying prescribing information.
Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container.
Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.

Manufactured by:
Glenmark Pharmaceuticals Ltd.
Colvale-Bardez, Goa 403513, India
GO/DRUGS/648
Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
09/19

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

PE444150919-1

JAR SIZE : 250 CC
SAME SIZE ARTWORK
LABEL SIZE : 130 mm x 55 mm

UNAPPROVED AREA
32 mm x 25 mm

Carvedilol Tablets USP 25mg (500 Tablets in Container)

JAR SIZE : 250 CC
SAME SIZE ARTWORK
LABEL SIZE : 130 mm x 55 mm

NDC 68462-165-05 Carvedilol Tablets, USP 25 mg glenmark	
Rx Only	500 Tablets

Each tablet contains carvedilol USP, 25 mg.
Product meets USP Dissolution Test 2
Usual Dosage: See accompanying prescribing information.
Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container.

Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.

Manufactured by: **Glenmark Pharmaceuticals Ltd.**
Colvale-Bardez, Goa 403513, India
GO/DRUGS/648
Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
09/19

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

PE444170919-1

UNAPPROVED AREA
32 mm x 25 mm

JAR SIZE : 40 CC
SAME SIZE ARTWORK
LABEL SIZE : 105 mm x 30 mm

UNVARNISHED AREA
32 mm x 30 mm

NDC 68462-162-01
**Carvedilol
Tablets, USP**
3.125 mg
glenmark

Rx Only 100 Tablets

Each tablet contains carvedilol USP 3.125 mg.
Product meets USP Dissolution Test 2.
Keep this and all other medications out of the reach of children.
Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from light.
Important: Use safety closures when dispensing this product unless otherwise indicated by physician or requested by purchaser.
Manufactured by: Glenmark Pharmaceuticals Ltd., Glenmark Pharmaceuticals Inc., USA
Manufactured for: Glenmark Pharmaceuticals Inc., USA
Lot: 0919
PE4478019-1
Questions? 1 (800) 721-7115
www.glenmarkpharm.com

May
Breedlove

Digitally signed by
May Breedlove
Date: 2019.11.06
10:08:17 -05'00'

Donna-
Marie
Walters

Digitally signed
by Donna-Marie
Walters
Date: 2019.11.06
10:40:53 -05'00'

Carole
Capella

Digitally signed
by Carole Capella
Date: 2019.11.06
12:54:53 -05'00'

MINIMUM FONT SIZE: 3.9 PT

GLENMARK PHARMACEUTICALS LTD.		DATE:	PANTONE SHADE ID: BLACK 1 86 C
PRODUCT NAME: Carvedilol Tablets USP 3.125 mg		PKG. DEV.:	Item code, Version, Consistency of Design, Overprint area, Pack size, Dimensions & Layout
ITEM CODE: PE44476 VERSION: 0919-1		RA	Regulatory Test
PHARMACODE:		QA:	Entire Test
COUNTRY: USA		PRODUCTION:	Machine Suitability
LOCATION: GOA		REMARKS:	
PACK: LABEL - 100 TABLETS			
ACTUAL SIZE: 105 mm x 30 mm			
SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED			

UNVARNISHED AREA
32 mm x 30 mm[illegible]

Digitally signed by
May Breedlove
Date: 2019.11.06
10:17:39 -05'00'

Donna-Marie Walters

Digitally signed by
Donna-Marie
Walters
Date: 2019.11.06
10:41:32 -05'00'

Carole
Capella

Digitally signed
by Carole Capella
Date: 2019.11.06
12:55:03 -05'00'

MINIMUM FONT SIZE: 3.9 PT

B GLENMARK PHARMACEUTICALS LTD.		DATE:		PANTONE SHADE #:  of LACK	
PRODUCT NAME: Carvedilol Tablets USP 3.125 mg		PKG. DEV.:		1: 86 C	
ITEM CODE: PE44477 VERSION: 0919-1		RA		Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
PHARMACODE:		QA:		Regulatory Text	
COUNTRY: USA		PRODUCTION:		Machine Suitability	
LOCATION: GOA		REMARKS:			
PACK : LABEL - 500 TABLETS					
ACTUAL SIZE: 105 mm x 30 mm					
SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED					

JAR SIZE : 190 CC
SAMPLE SIZE : ARTWORK
LABEL SIZE : 150 mm x 80 mm

NDC 68462-164-05

Carvedilol Tablets, USP

12.5 mg



Rx Only 500 Tablets

Each tablet contains carvedilol USP, 12.5 mg.
Product meets USP Dissolution Test 2
Usual Dosage: See accompanying prescribing information.
Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container. Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.

Manufactured by:
Glenmark Pharmaceuticals Ltd.
Colvale-Bardez, Goa 403513, India
GO/DRUGS/648
Manufactured for:
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430
09/19



Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

PE444150919-1

May
Breedlove

Digitally signed by
May Breedlove
Date: 2019.11.06
16:06:50 -05'00'

Donna-Marie
Walters

Digitally signed by
Donna-Marie Walters
Date: 2019.11.06
10:38:21 -05'00'

MINIMUM FONT SIZE: 5.1 PT

Carole
Capella

Digitally signed
by Carole Capella
Date: 2019.11.06
12:54:01 -05'00'

GLENMARK PHARMACEUTICALS LTD.	
PRODUCT NAME: Carvedilol Tablets USP 12.5 mg	DATE:
ITEM CODE: PE4415 VERSION: 0919-1	PKG. DEV.:
PHARMACODE:	RA
COUNTRY: USA	QA:
LOCATION: GOA	PRODUCTION:
PACK: LABEL - 500 TABLETS	Machine Suitability
ACTUAL SIZE: 130 mm x 50 mm	REMARKS:
SPECIFICATION: A UV VARNISH COATED FASTPRINT NONPERMANENT (HITAC)/PET 23 STICKER LABEL FROM AVERY	
DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED	

PANTONE SHADE NO. BLACK 186 C 143 C

Item code, Version, Consistency
of Design, overprint area, Pack
size, Dimensions & Layout

Regulatory Text

Entity Text

Machine Suitability

UNPRINTED AREA
35 mm x 152 mm

GLENMARK PHARMACEUTICALS LTD.		PRODUCT NAME: Carvedilol Tablets USP 25 mg		ITEM CODE: PE44417		VERSION: 0919-1		PHARMACODE: USA		LOCATION: GOA		PACK : LABEL - 500 TABLETS		ACTUAL SIZE: 130 mm x 55 mm	
DATE:		PKG. DEV.:		RA		QA:		PRODUCTION:		REMARKS:					
PANTONE SHADE NO. BLACK 364 C 186 C		Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout		Regulatory Text		Entire Text		Machine Suitability							

DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED

May Breedlove
 Digitally signed by May Breedlove
 Date: 2019.11.06 10:07:34 -05'00'

Donna-Marie Walters
 Digitally signed by Donna-Marie Walters
 Date: 2019.11.06 10:40:24 -05'00'

Carole Capella
 Digitally signed by Carole Capella
 Date: 2019.11.06 12:54:32 -05'00'

Rx Only **500 Tablets**

Carvedilol Tablets, USP

25 mg

glenmark

NDC 68462-165-05

Each tablet contains carvedilol USP 25 mg.
 Product meets USP Dissolution Test 2
Usual Dosage: See accompanying prescribing information.
 Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container.
Important: Use safety closures when dispensing this product unless otherwise directed by physician or requested by purchaser.
 Manufactured by: Glenmark Pharmaceuticals Ltd., Covale-Bardez, Goa 403513, India
 GO/RUGS/648
 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430 09/19
 PE4417819-1

Questions? 1 (888) 721-7115
 www.glenmarkpharma-us.com

JAR SIZE : 250 CC
 SAME SIZE ARTWORK
 LABEL SIZE : 130 mm x 55 mm
 UNVARNISHED AREA 32 mm x 55 mm

May Breedlove
Digitally signed by
Carole Capella
Date: 2023.08.29
09:49:07 -0400
Digitally signed by
Dhara Tailor
Date: 2023.08.29
09:56:10 -0500

PRODUCT NAME: GLENMARK PHARMACEUTICALS LTD
ITEM CODE: CESTAS4, VERSION: 0823-1
PHARMACODE: MA BARCODE: 084930
COUNTRY: US
LOCATION: Glandorp
PACT: Filled glass vials (3x30ml)
ACTUAL SIZE: 610X340 MM
REPRODUCTION: 40 CM Blank Paper
REMARKS: NA
DATE: 2023.08.29
FPC0001/01.00

What is high blood pressure?
High blood pressure is a condition in which the force of the blood against the artery walls is too high. It is often called a "silent killer" because it usually has no symptoms. High blood pressure can lead to heart disease, stroke, and kidney failure. It is most common in people over the age of 40, but it can also affect younger people. High blood pressure is often caused by a combination of factors, including genetics, diet, and lifestyle. It can be treated with medication and lifestyle changes.

What is high blood pressure?
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What is high blood pressure?
High blood pressure is a condition in which the force of the blood against the artery walls is too high. It is often called a "silent killer" because it usually has no symptoms. High blood pressure can lead to heart disease, stroke, and kidney failure. It is most common in people over the age of 40, but it can also affect younger people. High blood pressure is often caused by a combination of factors, including genetics, diet, and lifestyle. It can be treated with medication and lifestyle changes.

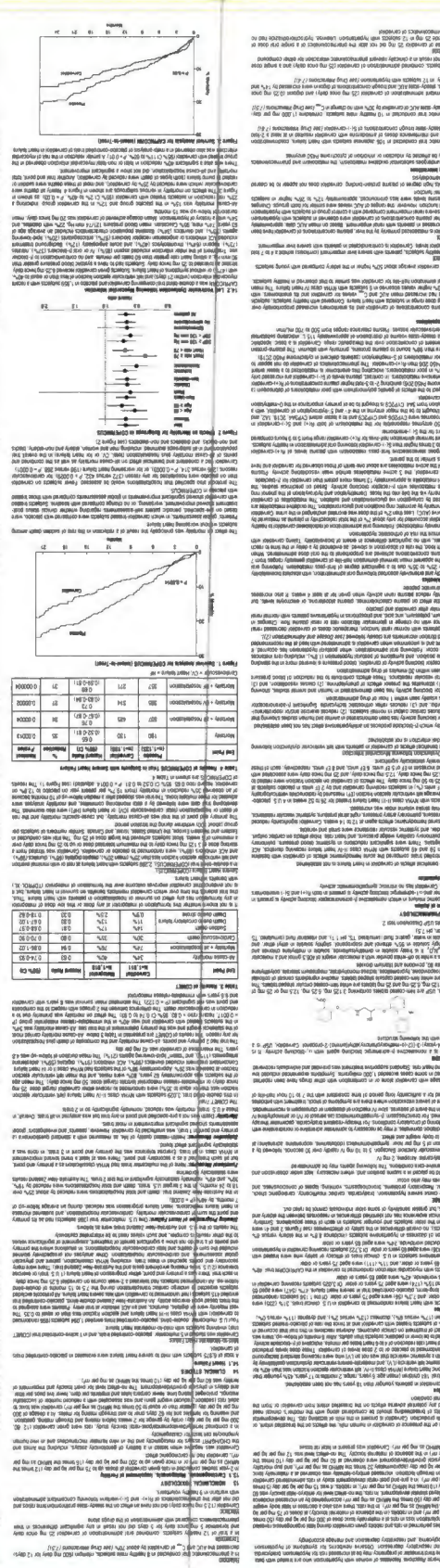


Figure 1: Trends in blood pressure over time. The graph shows a steady increase in blood pressure over the course of the study. The data points are plotted against time, and a trend line is drawn through them. The trend line shows a positive correlation between time and blood pressure.

Figure 2: Trends in blood pressure over time. The graph shows a steady increase in blood pressure over the course of the study. The data points are plotted against time, and a trend line is drawn through them. The trend line shows a positive correlation between time and blood pressure.

Figure 3: Trends in blood pressure over time. The graph shows a steady increase in blood pressure over the course of the study. The data points are plotted against time, and a trend line is drawn through them. The trend line shows a positive correlation between time and blood pressure.

Glenmark Pharmaceuticals Inc.
RECALL RETURN RESPONSE FORM
CARVEDILOL TABLETS USP 3.125mg, 12.5mg, and 25mg
100s and 500s Container pack
NDC 68462-162-01, 68462-162-05, 68462-164-05, 68462-165-05
Retail Level
07 August 2025

Please fill out this form completely. By doing so, this will acknowledge that you have read and understood the recall instructions and have taken the appropriate action.

Customer Name:	DEA#:
<i>DEA # is required, if it is not provided, the processing of your form will be delayed.</i>	
Address:	
City:	State: Zip:
Contact Name (Please Print):	
Telephone#:	Email:
Contact Signature:	Date:
DEBIT MEMO# (If unsure, leave blank):	

Wholesaler Information if not directly purchased from Glenmark Pharmaceuticals Inc.:

Wholesaler Name:	DEA#:
City:	State: Zip:

I have checked my stock and communicated to my customers at the appropriate level:

☐ I confirm that all locations that received the impacted products have been notified to the Retail level
 _____ (Initial and date)

☐ I do not have any stock of the recalled items.

OR

☐ I have quarantined and listed in the box below the quantity of recalled units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) Please indicate the # of needed box labels _____

Carvedilol Tablets USP 3.125mg (100's Tablets)

Sr. No.	Product Name	NDC Code	Batch Number	Pack Size	Expiry Date	Total Full/ Sealed and Partial/ Open Bottle Count
1	Carvedilol Tablets USP 3.125mg	68462-162-01	19242272	100's Tablets in Container	May-26	

Carvedilol Tablets USP 3.125mg (500's Tablets)

Sr. No.	Product Name	NDC Code	Batch Number	Pack Size	Expiry Date	Total Full/ Sealed and Partial/ Open Bottle Count	
1	Carvedilol Tablets USP 3.125mg	68462-162-05	19242274	500's Tablets in Container	May-26		
2	Carvedilol Tablets USP 3.125mg	68462-162-05	19242275	500's Tablets in Container	May-26		
3	Carvedilol Tablets USP 3.125mg	68462-162-05	19242272	500's Tablets in Container	May-26		

Carvedilol Tablets USP 12.5mg (500's Tablets)

Sr. No.	Product Name	NDC Code	Batch Number	Pack Size	Expiry Date	Total Full/ Sealed and Partial/ Open Bottle Count	
1	Carvedilol Tablets USP 12.5mg	68462-164-05	19243202	500's Tablets in Container	Jul-26		

Carvedilol Tablets USP 25mg (500's Tablets)

Sr. No.	Product Name	NDC Code	Batch Number	Pack Size	Expiry Date	Total Full/ Sealed and Partial/ Open Bottle Count	
1	Carvedilol Tablets USP 25mg	68462-165-05	19243104	500's Tablets in Container	Jul-26		

If you have any questions regarding this form or product return please contact Inmar at 855-709-6717 Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com
Recall Event ID N131326 | RCL154-25

his system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on
om. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage,
non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document
tual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from
or any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and
prms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized
d value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$1,000, e.g.
, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed
strict time limits, see current FedEx Service Guide.

OPEN IMMEDIATELY

**URGENT
RECALL
INFORMATION**

**ATTN: FEDEX CSR
If Undeliverable DESTROY,
do not return to shipper**

printing this label:
SIGNEE COPY - PLEASE PLACE IN FRONT OF POUCH
d the printed page along the horizontal line.
ce label in shipping pouch and affix it to your shipment.

ORIGIN ID:INTA (800) 868-5377
RECALL DEPARTMENT
INMAR
ONE WEST FOURTH STREET
SUITE 500
WINSTON SALEM, NC 27101
UNITED STATES US

SHIP DATE: 07AUG25
ACTWGT: 0.20 LB MAN
CAD: 0632402/CAFE3907
BILL THIRD PARTY

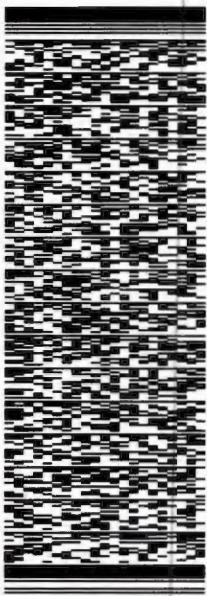
TO **RISK/RECALL MANAGER**
INDEPENDENT PHARMACY DIST WH2
1107 WEST MARKET CENTER

HIGH POINT NC 27260

(800) 868-5377

REF: ROL154-25

INV: 410-1817



4251824111481us

58CC2/E4ED/FE2D

TRK# 0201 4759 8603 3582

FRI - 08 AUG 5:00P
STANDARD OVERNIGHT

24 DUFA

ASR 27260
NC-US GSO

