URGENT DRUG RECALL
Nortrel® and Nortrel® 7/7/7
(norethindrone and ethinyl estradiol tablets USP)
January 25, 2024

Teva Pharmaceuticals USA, Inc.

Nortrel® and Nortrel® 7/7/7 (norethindrone and ethinyl estradiol tablets USP)						
Label	Lot #	Exp. Date	Strength	Size	Carton NDC	Blister NDC
Nortrel®	100042978	07/2024	0.5 mg /0.035 mg	3 Blister Cards, 28 Tablets Each	0555-9008-67	0555-9008-79
Nortrel®7/7/7	100040731	07/2024	0.5 mg /0.035 mg 0.75 mg /0.035 mg 1 mg /0.035 mg	6 Blister Cards, 28 Tablets Each	0555-9012-58	0555-9012-79

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (TEVA USA) is initiating a voluntary nationwide recall of the above referenced drug products to the **RETAIL LEVEL.** The products in this recall were distributed to TEVA USA direct customers under the Teva Pharmaceuticals USA, Inc. label. The reason for the recall is there is a possibility of discolored tablets (shades of blue) mixed in with the white inert 'reminder' tablets. The discolored reminder tablets may contain trace amounts of estradiol active pharmaceutical ingredient (API). The inert 'reminder' tablets should contain no API. Test samples have shown that the trace quantities of estradiol API in the discolored 'reminder' tablets are at or below 10% of the established Acceptable Daily Exposure (ADE) limit of the estradiol API of 2.0 mcg/tablet. The trace amounts of estradiol API in the reminder tablets of the affected lots are not expected to cause additional side effects or adverse health consequences.

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

Please take the following actions upon receipt of this letter:

- Immediately examine your inventory for the specified lots being recalled.
- Immediately discontinue distribution of the specific lots being recalled.
- TEVA's records indicate that the specified lots were commercially distributed/shipped to its direct customers:

Product Name	Lot #	Distribution / Shipped Dates
Nortrel®	100042978	From 6/27/2023 through 09/5/2023
Nortrel®7/7/7	100040731	From 4/6/2023 through 9/5/2023

- **If you have further distributed the recall lots, please perform a SUB-RECALL to your sub-accounts using this Recall Notification and Business Reply Form (BRF) as a basis for your recall notification.**
- Promptly complete the attached Recall BRF, even if you have **no** product to return, and return the completed Recall BRF to Inmar, Attn: Recall Coordinator by any one of these means:

  MAIL: Inmar, One West Fourth Street, Suite 500, Winston Salem, NC 27101
  EMAIL: **rxrecalls@inmar.com**.
  FAX: 817-868-5362.

After receipt of your Recall BRF, Inmar will send labels for your Return Goods Authorization (RGA) and shipping of your product return. Appropriate credit for your product returns, plus expenses for handling and shipping, will be issued after receipt of said product with your RGA. All recalled product returned without a RGA will delay the issuance of a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT
Product Returns: Contact Inmar at 877-801-5154 (Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Business Stock Response forms or acquire from clsnetlink.com
Medical-related Questions or to report an Adverse Event: Contact Teva Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at druginfo@tevapharm.com
Product Quality Complaint-related Questions: Contact Teva Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at QAS@tevapharm.com
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3, then option 2 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

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(norethindrone and ethinyl estradiol tablets USP)
January 25, 2024

RECALL BUSINESS REPLY FORM

Date Form Completed _____

Promptly return your completed Business Reply Form (BRF) by any one of these means to Inmar, Attn: Recall Coordinator
MAIL: Inmar, 1 W 4th St., Winston Salem, NC 27101 EMAIL: rxrecalls@inmar.com FAX: 817-868-5362

Section 1 – Customer Information

This Stock Response is for (Check One): ☐ **Teva Direct Account** ☐ **Non-Direct Customer**

Customer/Store Name:	Address (Street/City/State/Zip)
*DEA #: ***DEA # is required; in order to process your form.***	*Debit Memo #
Contact Name (please print):	Telephone #:

Please mark your answer - I have checked my stock and):

☐ I ***do*** have stock of the recalled item(s) **(complete section 2)** **OR** ☐ I **do not** have stock of the recalled item(s).

Teva Direct Accounts
Does your response include **all** your DC locations? ☐ YES ☐ NO

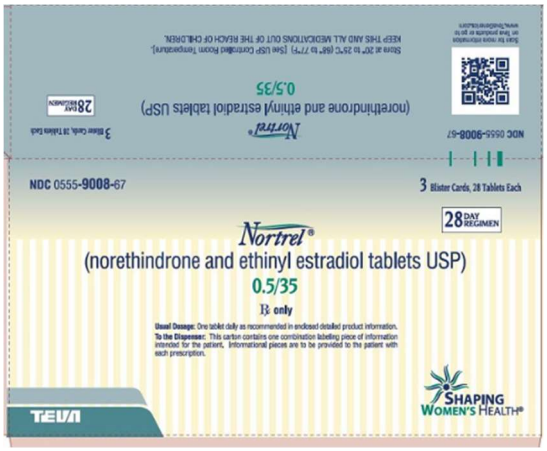
Non-Direct Customer
The product(s) in this recall were purchased from: _____ / Location: _____

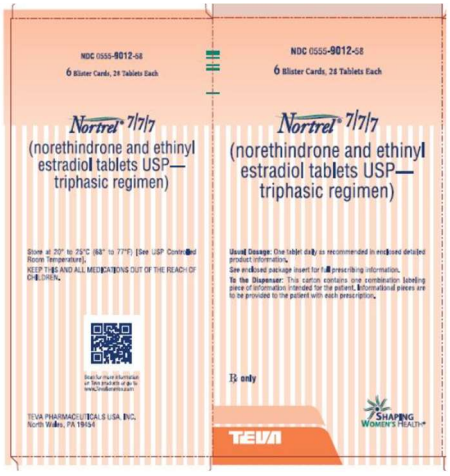
Section 2– Wholesalers/Distributors/Retailers – Quantity of Product to Return

Enter the information of the recalled product(s) to be returned in the table below. If additional space is needed, please make copies of this form.

Product Name	Lot #	Quanty of product to return. (count partial cartons as 1)
Nortrel®	100042978	
Nortrel®7/7/7	100040731	

Images Shown Have Not Been Reproduced to Scale of Actual Product Cartons





Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B