Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 01/31/18

Fentanyl Transdermal System CII 25 mcg/h, 50 mcg/h, 75 mcg/h and 100 mcg/h

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

Lot # / Exp. Date	Strength	Pack Size	NDC Pouch (Individual Transdermal Systems)	NDC Carton
All Lots within Expiry	25 mcg/h	5 Transdermal Systems / Carton	0591-3198-54	0591-3198-72
All Lots within Expiry	50 mcg/h	5 Transdermal Systems / Carton	0591-3212-54	0591-3212-72
All Lots within Expiry	75 mcg/h	5 Transdermal Systems / Carton	0591-3213-54	0591-3213-72
All Lots within Expiry	100 mcg/h	5 Transdermal Systems / Carton	0591-3214-54	0591-3214-72

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling all lots within expiry of **Fentanyl Transdermal System CII, 25 mcg/h, 50 mcg/h, 75 mcg/h and 100 mcg/h** distributed under the **Actavis Pharma Inc. label.** This recall is being carried out to the **RETAIL LEVEL** as the Fentanyl-n-Oxide (FNO) degradant exceeded the specification limits for the lots within scope of this recall. A complete list of the recalled lots accompanies this letter in the attached Stock Response Form.

The presence of Fentanyl-N-Oxide (FNO) in an affected product is not expected to pose a safety concern to the consumer. The probability of serious adverse health consequences is remote although use of or exposure to affected product might cause temporary or medically reversible adverse events.

Wholesalers / Distributors / Retailers - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Fentanyl Transdermal System CII, 25 mcg/h, 50 mcg/h, 75 mcg/h and 100 mcg/h.**
- Our records indicate we shipped this product between April 27, 2016 and January 24, 2018.
- Immediately discontinue distribution of the specific lots being recalled.
- **Wholesalers/Distributors/Retailers, if you have further distributed the specific lot, please perform a SUB-RECALL to your retail accounts using this Recall Notification and Stock Response Form.**
- Even if you have **no** product to return, promptly complete the attached recall stock response form (SRF) and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator,
  Inmar, 635 Vine Street, Winston Salem, NC 27101
  Email address: **rxrecalls@inmar.com.**
  FAX: 817-868-5362.

Inmar will send a Return Goods Authorization label and shipping label if requested on your SRF. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of product with the Return Goods Authorization form. All recalled product returned without a Return Goods Authorization label may delay the issuance of your 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: 800-967-5952. (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response forms Contact Inmar at: 800-967-5952 or acquire it from clsnetlink.com.
Customer Service-related Questions: Contact Teva Customer Service: 800-545-8800 (Hours of Operation: Live calls received: Monday-Friday, 8:30AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week).
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 3, then, option 3 (Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/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.

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STOCK RESPONSE FORM (Page 1 of 2)

Please fill out completely **Date:** _____

DIRECT CUSTOMERS ONLY: Does this response include **all** DC locations? ☐ YES ☐ NO

Customer/Store Name: _____ DEA #: _____

DEA # is required; if not provided the processing of your form will be delayed

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

I have checked my stock (for the recalled lots listed on page 2 of this form) and:

_____ I **do not** have stock of the recalled item(s) **OR** _____ I **do** have stock of the recalled item(s) listed above.

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name): _____ DEA #: _____

City: _____ State: _____

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STOCK RESPONSE FORM (Page 2 of 2)

Lot	Exp. Date	Strength	Size	Quantity to Return: If Single Pouches NDC 0591-3198-54	Quantity to Return: If Full Carton(s) NDC 0591-3198-72
1086848A	Jan-18	25 mcg/h	5 Pouch Carton		
1103907A	Mar-18	25 mcg/h	5 Pouch Carton		
1114170A	Apr-18	25 mcg/h	5 Pouch Carton		
1117212A	May-18	25 mcg/h	5 Pouch Carton		
1130863A	Jul-18	25 mcg/h	5 Pouch Carton		
1140570A	Jul-18	25 mcg/h	5 Pouch Carton		
1153178A	Aug-18	25 mcg/h	5 Pouch Carton		
1153185A	Sep-18	25 mcg/h	5 Pouch Carton		
1171608A	Nov-18	25 mcg/h	5 Pouch Carton		
1188715A	Jan-19	25 mcg/h	5 Pouch Carton		
1193264A	Apr-19	25 mcg/h	5 Pouch Carton		
1208789A	Apr-19	25 mcg/h	5 Pouch Carton		
1212340A	Jul-19	25 mcg/h	5 Pouch Carton		
1225166A	Jul-19	25 mcg/h	5 Pouch Carton		
1238442A	Aug-19	25 mcg/h	5 Pouch Carton		
				Quantity to Return: If Single Pouches NDC 0591-3212-54	**Quantity to Return: If Full Carton(s) NDC 0591-3212-72**
1090258A	Jan-18	50 mcg/h	5 Pouch Carton		
1103917A	Feb-18	50 mcg/h	5 Pouch Carton		
1114192A	Apr-18	50 mcg/h	5 Pouch Carton		
1125605A	Jun-18	50 mcg/h	5 Pouch Carton		
1138897A	Aug-18	50 mcg/h	5 Pouch Carton		
1153171A	Aug-18	50 mcg/h	5 Pouch Carton		
1156261A	Oct-18	50 mcg/h	5 Pouch Carton		
1171595A	Nov-18	50 mcg/h	5 Pouch Carton		
1179544A	Jan-19	50 mcg/h	5 Pouch Carton		
1189531A	Mar-19	50 mcg/h	5 Pouch Carton		
1211389A	May-19	50 mcg/h	5 Pouch Carton		
1227468A	Jun-19	50 mcg/h	5 Pouch Carton		
1231784A	Sep-19	50 mcg/h	5 Pouch Carton		
1232943A	Sep-19	50 mcg/h	5 Pouch Carton		
				Quantity to Return: If Single Pouches NDC 0591-3213-54	**Quantity to Return: If Full Carton(s) NDC 0591-3213-72**
1086842A	Jan-18	75 mcg/h	5 Pouch Carton		
1107745A	Mar-18	75 mcg/h	5 Pouch Carton		
1122452A	Jun-18	75 mcg/h	5 Pouch Carton		
1137109A	Jun-18	75 mcg/h	5 Pouch Carton		
1144515A	Oct-18	75 mcg/h	5 Pouch Carton		
1189477A	Mar-19	75 mcg/h	5 Pouch Carton		
1215224A	Aug-19	75 mcg/h	5 Pouch Carton		
				Quantity to Return: If Single Pouches NDC 0591-3214-54	**Quantity to Return: If Full Carton(s) NDC 0591-3214-72**
1096857A	Feb-18	100 mcg/h	5 Pouch Carton		
1115872A	Apr-18	100 mcg/h	5 Pouch Carton		
1123625A	May-18	100 mcg/h	5 Pouch Carton		
1148775A	Aug-18	100 mcg/h	5 Pouch Carton		
1157255A	Aug-18	100 mcg/h	5 Pouch Carton		
1169928A	Nov-18	100 mcg/h	5 Pouch Carton		
1196300A	Apr-19	100 mcg/h	5 Pouch Carton		
1213533A	Jun-19	100 mcg/h	5 Pouch Carton		

Please FAX this form to: 817-868-5362 or E-mail at: rxrecalls@inmar.com or mail to: Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B

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