URGENT DRUG RECALL
FENTANYL Buccal Tablets CII
Initiated 04/27/2023

Teva Pharmaceuticals USA, Inc.

Mayne Pharma
3301 Benson Drive, Suite 401
Raleigh, NC 27609

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is voluntarily recalling specific lots of various strengths of **FENTANYL Buccal Tablets CII** to the Consumer Level. Teva USA manufactured and labeled these product lots exclusively for Mayne Pharma Inc. under Mayne's label. Please refer to Attachment 1 for the list of the specific lots being recalled.

This recall has been initiated because safety updates were omitted in the Product Insert/Medication Guide (MG) that are provided with these recalled lots. Teva's Health Hazard Assessment concluded that the main safety concern is a potential for incomplete information needed by health care providers and patients regarding safe use of the product. Not following, or not being aware of, the omitted safety updates in the Product Insert/Medication Guide (MG) could lead to life-threatening adverse events; although, based on a Health Hazard Assessment conducted by Teva, the likelihood of the harm occurrence is considered remote. To date, Teva has not received any complaints related to the product labeling.

Please take the following necessary **ACTIONS** stated below.

ACTIONS: Please promptly perform the following actions that are necessary for this recall:

- Examine your inventory for the above drug product NDC and Lot numbers.
- Teva's distribution records show the recalled lots were distributed to you from 08/17/2020 through 01/18/2022.
- Quarantine and cease distribution of the product lots indicated for this recall.
- Promptly complete the enclosed Business Response Form (BRF), even if you have no product to return.
- Promptly return your completed BRF by any one of these means to Inmar, Attn: Recall Coordinator:

  MAIL: Inmar, 635 Vine Street, Winston Salem, NC 27101
  EMAIL: rxrecalls@inmar.com
  FAX: 817-868-5362.

- Please notify your direct accounts, asking them to perform a SUB-RECALL to their accounts, using this recall letter and BRF as a basis of your recall notification.

After receipt of your completed BRF, if you have recorded product to return, Inmar will send labels for Return Goods Authorization (RGA) and the return shipping labels. Appropriate credit for your product returns, plus handling and shipping expenses, will be issued after receipt of said product and your RGA. All recalled product returned without a RGA may delay the issuance of a credit. Any products that are returned, which are not the subject of the recall will not be credited and will be destroyed.

**** NOTE: DO NOT return product until you have received the product return package, which includes Return Goods Authorization label, Shipping Label and DEA 222 form. A copy of the completed DEA 222 form is required to process your return.***

CONTACT INFORMATION AND CREDIT
Product Returns: Contact Inmar at: 855-246-5024 (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response Forms - Contact Inmar at 855-863-0535 or acquire forms from clsnetlink.com.
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-483-8279 or USMedInfo@tevapharm.com Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Product Quality Complaint-related Questions: Contact 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
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3 then, option 2 Live calls received: M - F, 8:30 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

Teva also wishes to advise you that the recall notification will appear on its webpage (www.TevaUSA.com in the News & Media section), which will include instructions for consumers to return any recalled product in their possession.

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

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

Attachment 1 FENTANYL Buccal Tablets CII Recalled Product Lots				
NDC#	Lot	Exp. Date	Strength	Size
51862-634-28	42617828	06/2023	100 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-634-28	100020465	01/2024	100 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-635-28	100020528	09/2024	200 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-635-28	100026699	11/2024	200 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-636-28	100020351	11/2024	400 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-636-28	100020522	09/2024	400 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-636-28	100026700	11/2024	400 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-637-28	42617831	06/2023	600 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-637-28	42619585	11/2023	600 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-637-28	100029649	11/2024	600 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-638-28	42617832	06/2023	800 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-638-28	42619530	08/2023	800 mcg	28 Buccal Tablets (4 tablets x 7 cards)
51862-638-28	100020532	11/2024	800 mcg	28 Buccal Tablets (4 tablets x 7 cards)

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RECALL BUSINESS RESPONSE FORM

Date Form Completed _____

Promptly return your completed SRF by any one of these means to Inmar, Attn: Recall Coordinator
MAIL: Inmar, 635 Vine Street, Winston Salem, NC 27101 EMAIL: rxrecalls@inmar.com FAX: 817-868-5362

Section 1 – Customer Information

Check One **This Stock Response is for:**	☐ **Teva Direct Account** ☐ **Non-Direct Customer**
Customer/Store Name:	
*DEA #: ***DEA # is required; in order to process your form.***	*Debit Memo #
Address:	City/State/Zip
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 CUSTOMERS ONLY: Please complete the following:

Wholesaler City / Wholesaler State	Wholesaler DEA #: ***DEA # is required; in order to process your form.***
Purchased From (Wholesaler name):	

Section 2 – 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.

NDC	Lot #	Exp. Date	Unit Size	Number of Full Cartons to Return*	Number of Tablets for Partial Boxes to Return*

*** Note: In order to generate the DEA 222 form for your return, please enter the correct number of full boxes and the count of tablets for partial boxes to return.***

Please indicate the number of shipping labels that you need to return the recalled product(s): _____

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