URGENT DRUG RECALL
Information for Consumers/Patients/Caregivers

Teva Issues Voluntary Nationwide Recall of Specific Lots of FENTANYL Buccal Tablets CII to the Consumer Level
Initiated April 27, 2023

Dear Valued Consumer/Patient/Caregiver:

At Teva, our first priority is to our customers and patients. We are committed to ensuring the safe and effective use of our products.

Teva Pharmaceuticals USA, Inc. (Teva) wishes to advise you of its voluntary nationwide recall of specific lots of various strengths of FENTANYL Buccal Tablets CII to the Consumer Level. The specific lots in this recall are given in Table 1 below. No other lots of FENTANYL Buccal Tablets are impacted.

Fentanyl Buccal Tablets, CII 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg tablets are manufactured by Teva Pharmaceuticals USA, Inc., and exclusively labeled for Mayne Pharma Inc. Teva shipped the recalled lots to Mayne Pharma Inc. from 08/17/2020 through 01/18/2022. Mayne Pharma Inc. commercially distributed the product to their customers.

Table 1
Specific Lots of Various Strengths of FENTANYL Buccal Tablets CII Being Recalled

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)

Reason for Drug Product Recall:

This voluntary nationwide recall of specific lots of **Fentanyl Buccal Tablets, CII 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg** was initiated because safety updates were omitted in the Product Insert/Medication Guide 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 could potentially lead to life-threatening adverse events; although, based on Teva's Health Hazard Assessment, the likelihood of the harm is considered remote. To date, Teva has not received any complaints related to the product labeling of the subject recalled product lots.

The complete updated prescribing information with new safety information, including boxed warning and Medication Guide is available on the National Library of Medicine Daily Med website, which provides the labeling for prescription products in the USA. Available at: DailyMed - FENTANYL BUCCAL- fentanyl citrate tablet (nih.gov).

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Returning the Recalled Drug Product:

As a Consumer/Patient/Caregiver, your first course of action should be to consult with your pharmacist, healthcare provider or physician who can advise you about a replacement prescription for your medication. The potential for adverse health consequences associated with stopping the medication may be of greater concern than continuing your medication as prescribed until a replacement product is provided by your healthcare providers.

Once your pharmacist, healthcare provider or physician has provided you with a replacement prescription to treat your condition, we request that you return any remaining product in your possession. Please contact Teva's product recall processor Inmar at 855 246 5024 (Dedicated Phone Line) or email Inmar at rxrecalls@inmar.com to obtain instructions for returning your medication.

Appearance and Description of FENTANYL Buccal Tablets CII being recalled:

To help you identify whether you have the drug product that is the subject of the recall, description of its appearance (RE: Table 2) and the product's carton labeling (RE: Table 3) are below. Each Fentanyl buccal tablets is flat-faced, round, beveled-edge in shape and white in color. Fentanyl buccal tablets are supplied in individually sealed, child-resistant blister packages. Each carton contains 7 blister cards with 4 white tablets in each card. The blisters are child-resistant, encased in peelable foil, and provide protection from moisture. Each tablet is debossed (marked) on one side with  , and on the other side, each dosage strength is uniquely identified by the debossing (code) on the tablet as described in the table 2 below. In addition, the dosage strength is indicated on the blister package and the carton.

Table 2
Appearance and Description of FENTANYL Buccal Tablets CII being recalled

Dosage Strength	Unique Debossing Code for Tablet Strength	Carton/Blister Package Color	NDC Number
100 mcg	1	Blue	51862-634-28
200 mcg	2	Orange	51862-635-28
400 mcg	4	Sage green	51862-636-28
600 mcg	6	Magenta (pink)	51862-637-28
800 mcg	8	Yellow	51862-638-28

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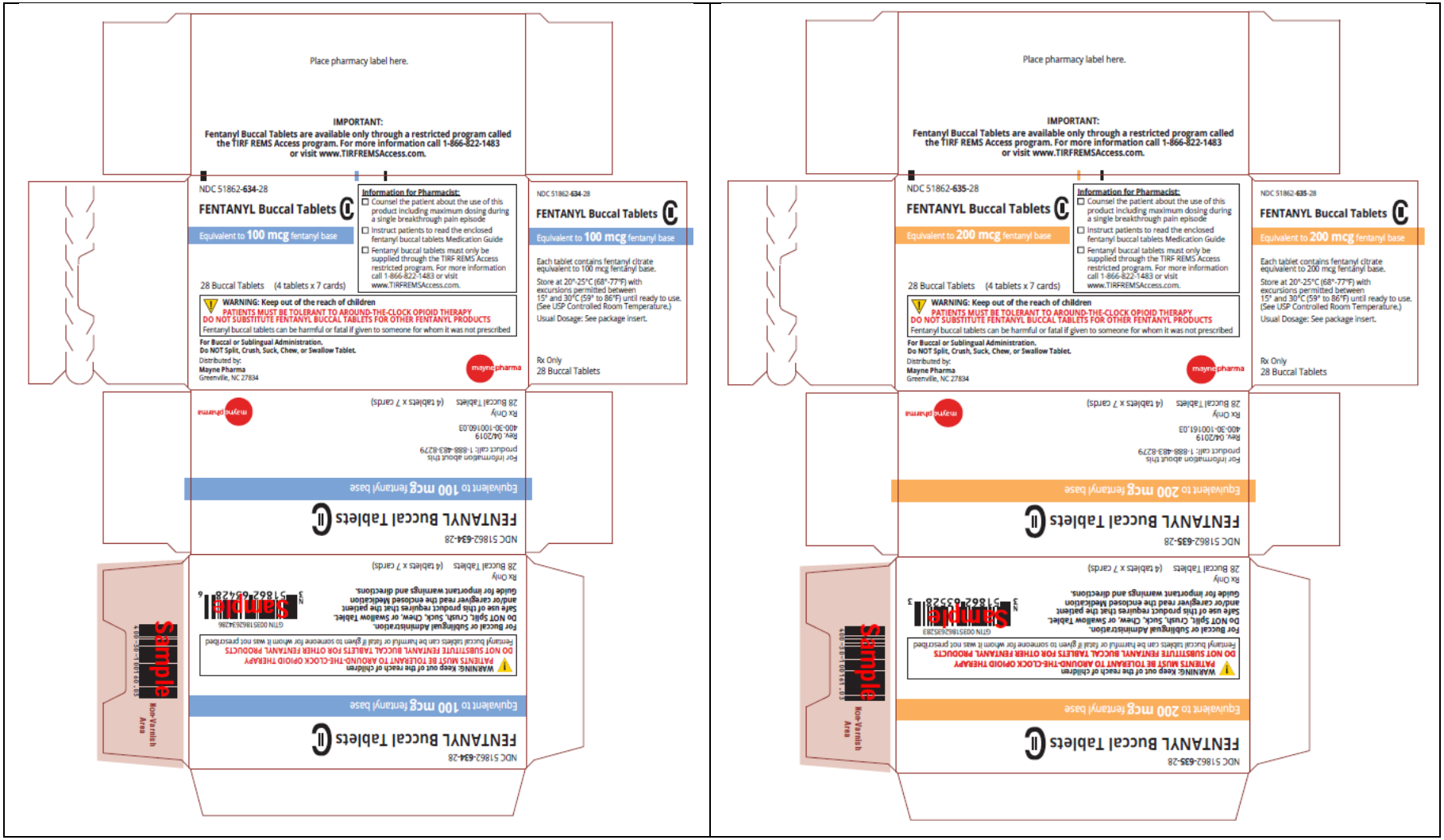
Table 3 Carton Labeling (100 mcg and 200 mcg)



Non-Varnish Area

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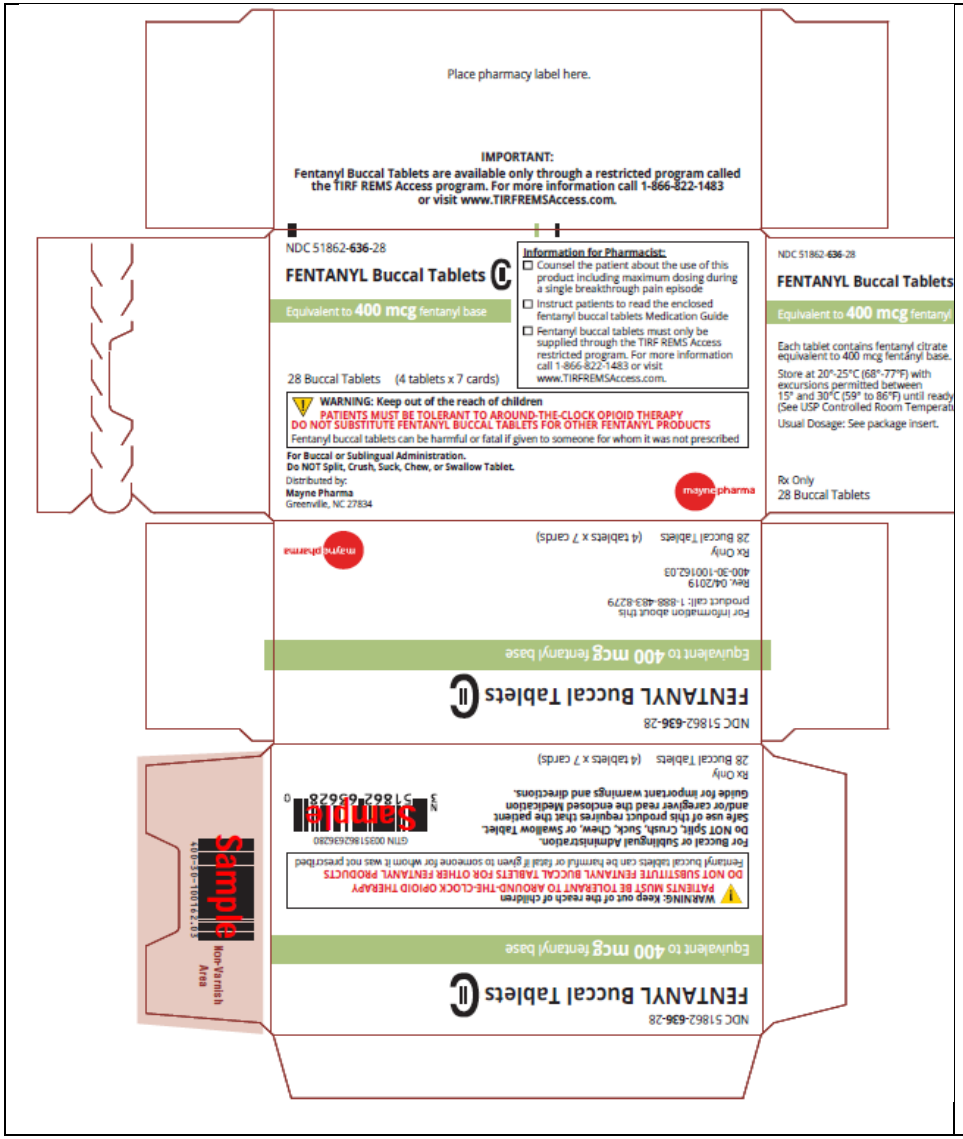
Table 3 Carton Labeling (400 mcg and 600 mcg)



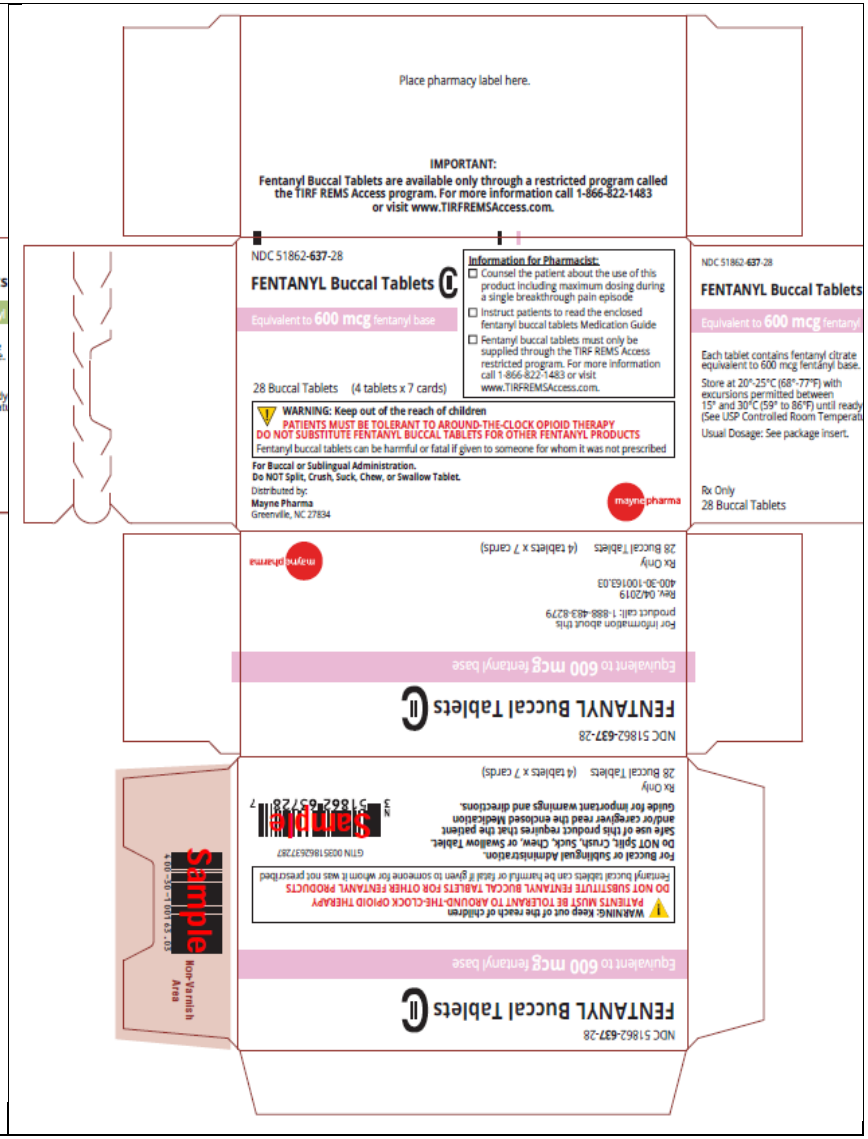


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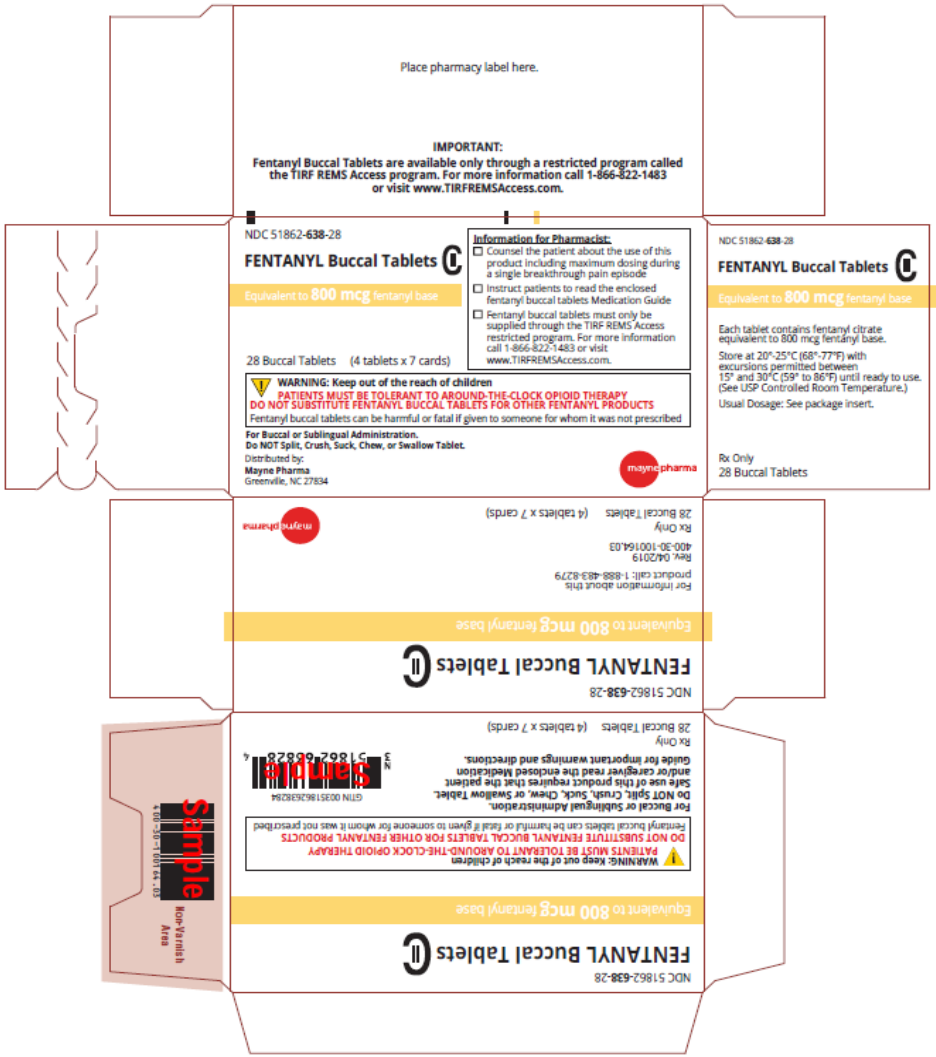
Table 3 Carton Labeling (800 mcg)



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Other Information:

Indications and Usage

Fentanyl buccal tablet is an opioid agonist indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg oral oxymorphone per day, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid. Patients must remain on around-the-clock opioids while taking fentanyl buccal tablet.

Important Contact Information

If you wish to report an Adverse Event or a Product Quality Complaint, or if you have Medical Related Questions, please contact Teva's Medical Information at: 888-483-8279. Live calls are received: Monday-Friday, 9:00 am - 5:00 pm Eastern Time and voicemail: 24 hrs/day, 7 days/week or by email at USMedInfo@tevapharm.com.

Adverse events or other problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program online or by regular mail or fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-1088.

Sincerely,

Regulatory Compliance
Teva Pharmaceuticals USA, Inc.