

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Teva Pharmaceuticals USA, Inc. (Teva USA) is 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.

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)