

Memorandum

To: Gold Coast Health Plan Providers

From: Lily Yip, Pharm.D., MBA, APH, CDCES, BCACP, CPHQ, Director of Pharmacy

Re: **FDA Drug Recall and Voluntary Market Withdrawal**

Date: Aug. 10, 2026

This is a notification regarding multiple Food and Drug Administration (FDA) drug recalls/voluntary manufacturer withdrawals that may impact Gold Coast Health Plan (GCHP) members. Please see below for detailed information regarding each affected product.

Recall/Withdrawal 1

Drug: Amlodipine-olmesartan 10 mg-20 mg tablet

Manufacturer: Ascend Laboratories

Reason for Recall/Withdrawal: Failed dissolution specification; Olmesartan medoxomil content below specifications

Effective Date: July 8, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Amlodipine-olmesartan	10-20mg	Tablet	67877-0500-30	25121311	March 31, 2028

FDA Recall/Withdrawal Notice:

<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=221449>

Manufacturer Communication: 1-877-272-7901 (24/7) or email contact@ascendlaboratories.com

Recall/Withdrawal 2

Drug: Cyproheptadine hydrochloride 2 mg/5 mL syrup

Manufacturer: Lyne Laboratories

Reason for Recall/Withdrawal: Presence of precipitate: medication was crystallizing and particles floating in the bottle

Effective Date: July 13, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Cyproheptadine hydrochloride	2mg/5 mL	Syrup	64980-0504-48.	CR2518	November 2027
				CR2601	December 2027
				CR2602, CR2603	January 2028
				CR2604, CR2605	February 2028

FDA Recall/Withdrawal Notice:

<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=221494>

Manufacturer Communication: 1-800-525-0450 or <https://lyne.com/contact-us/>

Recall/Withdrawal #3

Drug: Azelaic acid gel 15% 50 gm tubes

Manufacturer: Glenmark Pharmaceuticals Inc

Reason for Recall/Withdrawal: Product quality complaints concerning abnormal texture or consistency (described as grainy, gritty, or sandy) were received

Effective Date: July 23, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Azelaic acid gel	15%	Gel	68462-626-52	19260937A	February 2028
				19261225A, 19261185A	March 2028
				19261664A, 19261682A	April 2028

FDA Recall/Withdrawal Notice:

<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=221666>

Manufacturer Communication: 1-888-721-7115 9am-6pm EST (Monday - Friday) or email GlobalCustomerService@glenmarkpharma.com

Recall/Withdrawal #4

Drug: Dorzolamide hcl-timolol maleate 2%-0.5% ophthalmic solution 10 ml vial

Manufacturer: Micro Labs, USA, Inc.

Reason for Recall/Withdrawal: Defective Container - multiple complaints of broken cap spikes and undeliverable drop

Effective Date: July 22, 2026

Product Name	Strength	Dosage Form	NDC	Lot Number(s)	Expiration Date(s)
Dorzolamide hcl-timolol maleate	2%-0.5%	Ophthalmic solution	42571-147-26	DLHU0031	June 30, 2027

FDA Recall/Withdrawal Notice:

<https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=221668>

Manufacturer Communication: 855-839-8195, 9 a.m. – 5 p.m. EST (Monday – Friday)

Clinical Considerations

Providers should:

- Review patient records to identify individuals receiving affected product(s).
- Evaluate patients for potential clinical impacts related to the recall or withdrawal.
- Discontinue use of affected product(s) as appropriate.
- Transition patients to an appropriate alternative therapy when clinically indicated.
- Monitor patients for potential adverse events and/or treatment interruptions.

Member Notification

GCHP has identified and notified potentially affected members by letter regarding this drug recall/withdrawal.

Additional Information

For additional details regarding this drug recall/withdrawal, please refer to:

- [FDA Drug Safety Communications](#)
- [FDA Recalls, Market Withdrawals, & Safety Alerts](#)
- [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)
- [The FDA Weekly Enforcement Reports](#)

For additional questions, please email GCHP Pharmacy Services Department at Pharmacy@goldchp.org.