

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.

Astellas Pharma US, Inc. is recalling products listed below because bottles may contain empty capsules.

Transplant patients who consume empty PROGRAF or ASTAGRAF XL capsules may experience initiation of rejection of the transplanted organ, tissue, or cells, due to underimmunosuppression. In the case of life sustaining organ transplants such as a heart transplant (for which there is no permanent substitute such as hemodialysis in the case of a failed kidney transplant) if the transplant fails, the consequences of rejection initiated by ingesting empty capsules may be fatal.

To date, Astellas has not received any reports of adverse events related to this recall.

PRODUCT DESCRIPTION	NDC	UPC CODE	LOT NO.	EXP. DATE
PROGRAF® (tacrolimus) 0.5 mg capsules 100 capsules per bottle	0469-0607-73	3 04690 60773 1	0E3353D	03/2026
ASTAGRAF XL® (tacrolimus extended-release capsules) 0.5 mg capsules 30 capsules per bottle	0469-0647-73	3 04690 64773 7	0R3092A	03/2026