

*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.*

Novartis Pharmaceuticals Corporation is voluntarily recalling one lot (FX001691) of Sandimmune® Oral Solution, 100 mg/mL, from the US market. This lot is being recalled due to crystal formation observed in some of the bottles, which could potentially result in the incorrect dosing of patients. The Medical Risk Assessment concluded that the risk for incorrect dosing is possible and would depend on the amount of crystallization in the bottles, which is difficult to quantify.

**Product:** Sandimmune Oral Solution (cyclosporine oral solution, USP)

**NDC Number:** 0078-0110-22

**Lot Number:** FX001691

**Expiration Date:** 12/2025

**Date of Manufacture:** 01/23/2023

**Distribution Dates:** 04/20/2023 - 08/14/2023