

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.

On April 6, 2023, U.S Food and Drug Administration's decided to withdraw approval of Makena® (hydroxyprogesterone caproate injection) therefore Covis Pharma ("Covis") is initiating a voluntary withdrawal. The Center for Drug Evaluation and Research (CDER) has issued guidance recognizing that a limited supply of Makena has already been distributed and acknowledging some healthcare providers might continue to prescribe or administer that limited remaining supply to their patients. Covis recommends that you consider this guidance and FDA conclusion on the withdrawal of Makena.

Product: MAKENA 275MG/1.1ML

NDC: 64011-0301-03

Unit Size: 275MG