

Product Recall: Cequa TM (cyclosporine ophthalmic solution), 0.09%, 6 pouches x 10 single-use vials (0.25 mL each)

The Board of Pharmacy has received notice of the following product market withdrawal:

Description – Cequa TM (cyclosporine ophthalmic solution), 0.09%, 6 pouches x 10 single- use vials (0.25 mL each) Lot Number – 10006 NDC – 47335-506-96 Exp Date – 01/2022

Description – Cequa TM (cyclosporine ophthalmic solution), 0.09%, 6 pouches x 10 single- use vials (0.25 mL each) Lot Number – 10009 NDC – 47335-506-96 Exp Date – 03/2022

Sun Pharma sent a revision to an earlier letter dated May 5, 2021 in regards to the same lot numbers of Cequa™ (cyclosporine ophthalmic solution), 0.09% in the above table; Lots 10006 and 10009. Per FDA classification, this recall is revised from the depth of retail level to wholesale level. Additional information can be found in the product labeling.

This recall has been initiated due to laboratory results that indicate a lower than expected assay and elevated levels of particulate matter for Lot 10009. In addition to Lot 10009, Lot 10006 will also be recalled out of an abundance of caution as is manufactured using the same process, although there are no out of specification laboratory results at this time. Use of this product would lead to a lower dose administered to patients and may possibly cause discomfort in the eyes due to particulate matter. Sun Pharmaceutical Industries, Inc. initiated shipment of this product on August 26, 2020.

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