

Pine Pharmaceuticals
October 2, 2023
Re: Important Customer Information

Dear Customer,

Out of an abundance of caution, Pine has elected to issue a voluntary recall for several of our products. Please see supplemental documentation in this email for a complete list of impacted products, lot numbers, expiration dates, return procedure, and mandatory acknowledgment instructions.

This recall has been initiated due to an observation by the U.S. Food and Drug Administration (FDA) made during a routine inspection from September 6 – 19, 2023, citing a potential lack of sterility assurance for products intended to be sterile, resultant from a step in the inspection process isolated to the affected batches.

Adhering to the guidance outlined in the USP chapters on visual inspection (USP <790>, Visible Particulates in Injections, and <1790> Visual Inspection of Injections), Pine Pharmaceuticals performs a visual inspection on 100% of our sterile injectables, followed by an AQL (Acceptable Quality Limit) assessment, which gives statistical confidence to the initial inspection. The recalled batches involve cases where the AQL verification of the initial inspection prompted a second 100% visual inspection (200% total), followed by an additional, successful, AQL assessment.

Pine has taken immediate action to align with agency expectations, to include a full investigation in any event in which the initial 100% inspection is deemed unsuccessful through AQL verification. It is important to emphasize that 100% of the drug delivered to our customers has been manufactured in accordance with cGMP, including the completion of stringent, batch-specific testing requirements prior to release. There have been no known adverse events related to the sterility of the recalled products reported at this time.

Due to the isolated, process-oriented nature of these findings, we are confident that we have made the changes necessary to align with the agency's expectations. However, there may be temporary product shortages on select products. Our team will work diligently to fill orders as quickly as possible in the order in which they are received. Allocation may be implemented for order quantities until full production capacity has resumed.

We are committed to working with the U.S. Food and Drug Administration to manufacture in accordance with cGMP and maintain our good standing with the agency so we can continue to provide sterile, effective products you can count on. We thank you for your patience.