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 specific lots of repackaged bevacizumab (Avastin®). Please see supplemental documentation in this envelope 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 repackaged Avastin® intended to be sterile, when produced with specific equipment used in select fill lines. It is important to emphasize that 100% of the drug delivered to our customers has been manufactured in accordance with cGMP and has satisfied 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 by shifting production to lines that were unimpacted by FDA findings, we will align with the agency's expectations, and we will be able to supply drug again in a timely manner. While production has already resumed on unaffected lines, we anticipate a temporary product shortage of all repackaged bevacizumab syringes. In an effort to maintain continuity of patient care for all our customers, we ask that you order a one-week supply at a time until further notice. 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. Lastly, customers using item #987 (Norm-Ject® Less Fill, silicone-free syringe) will need to choose a different syringe as the production of this product is temporarily unavailable due to process limitations.

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.