

URGENT PRODUCT RECALL

October 2nd, 2023

Product Information: *See Attached for Affected Lot Numbers and Expiration Dates*

343	BEVACIZUMAB 1.25 MG/0.05 ML INJ - BD TB	608	TPC Drops 1% - 2.5% - 1% 5 mL
348	VANCOMYCIN (1 MG/0.1 ML) SDV	682	CALCIUM CL 20 MG/ML (500 ML) INJ
368	EK - CEF 22.5MG/ML - VANC 10MG/ML	740	LIDOCAINE HCL 4% (3 ML) OPHTH
392	CALCIUM GLUCONATE OPH 1% (500ML) SOL	762	TROPI-PHEN 1% - 2.5% OPHTH SOL (5 ML)
394	CALCIUM GLUCONATE 2.5% (5ML) INH	802	LIDO-OXY NS 2%-0.025% (2 ML) SYR
452	TROPI-PHEN 1%-2.5% OPHTH SOL (15 mL)	959	FOSCARNET 2.4 MG/0.1 ML SYR (0.2 ML)
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	963	BEVACIZUMAB 1.25MG/0.05ML INJ - SCLS MN
553	MOXIFLOXACIN IN BSS 150MCG/0.1ML SYR	987	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ LF
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR		
585	MOXIFLOXACIN IN BSS 100MCG/0.1ML SYR		
589	LIDO-PHEN 1%-1.5% (1ML) SDV		

Reason for Recall and potential hazards to patient:

This notification is to inform you of a recall involving certain lots of the above products within expiration from Pine Pharmaceuticals, LLC. The affected products were distributed from the facility between 05/03/2023 and 09/28/2023.

This recall has been initiated due to an observation by the U.S. Food and Drug Administration (FDA) of 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.

Administration of a drug product intended to be sterile that is not sterile could result in serious infections.

To date, Pine Pharmaceuticals has not received any reports of adverse events or patient injury related to the sterility of the listed drug products, but is issuing this recall out of an abundance of caution.

Instructions for product return:

1. Locate, isolate/quarantine, and prepare for return any unused affected product from your facility. Product does not need to be shipped under temperature controlled conditions.
2. Use included prepaid return label to ship product to Pine Pharmaceuticals to receive credit. **Include a copy of the Recall Acknowledgment Form with your return shipment.**
3. For additional questions, Pine Pharmaceuticals can be reached at 844-218-4138 between the hours of 9:00 am and 5:00 pm Eastern Standard Time, Monday through Friday or via support@pinepharmaceuticals.com
4. **You are required to complete and return the attached Recall Acknowledgment Form, even if you do not have any remaining inventory.**
5. Please report any complaints or adverse drug events with associated with this product quality@pinepharmaceuticals.com or via phone at 844-218-4138.

AFFECTED PRODUCTS AND LOTS

ITEM NUMBER	PRODUCT DESCRIPTION	LOT NUMBER	EXPIRATION DATE
343	BEVACIZUMAB 1.25 MG/0.05 ML INJ - BD TB	68861	10/13/2023
343	BEVACIZUMAB 1.25 MG/0.05 ML INJ - BD TB	69105	10/25/2023
343	BEVACIZUMAB 1.25 MG/0.05 ML INJ - BD TB	70204	11/24/2023
343	BEVACIZUMAB 1.25 MG/0.05 ML INJ - BD TB	70218	11/25/2023
348	VANCOMYCIN (1 MG/0.1 ML) SDV	69985	11/15/2023
368	EK - CEF 22.5MG/ML - VANC 10MG/ML	69986	11/15/2023
392	CALCIUM GLUCONATE OPH 1% (500ML) SOL	69802	2/28/2024
394	CALCIUM GLUCONATE 2.5% (5ML) INH	70363	3/20/2024
452	TROPI-PHEN 1%-2.5% OPHTH SOL (15 mL)	67008	10/4/2023
452	TROPI-PHEN 1%-2.5% OPHTH SOL (15 mL)	67685	10/21/2023
452	TROPI-PHEN 1%-2.5% OPHTH SOL (15 mL)	67853	10/25/2023
452	TROPI-PHEN 1%-2.5% OPHTH SOL (15 mL)	69967	1/13/2024
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68622	10/3/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68699	10/6/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68704	10/6/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68706	10/6/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68726	10/7/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68740	10/7/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68784	10/11/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68647	10/10/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68843	10/13/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68891	10/14/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68980	10/18/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	68983	10/21/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	69042	10/21/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	69077	10/26/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	69793	11/4/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	69796	11/9/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	69872	11/9/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	69928	11/11/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	69950	11/11/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	69988	11/15/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	69963	11/16/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70163	11/23/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70167	11/23/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70191	11/24/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70197	11/24/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70208	11/25/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70214	11/25/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70220	11/25/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70277	11/29/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70291	11/30/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70300	11/30/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70333	12/2/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70338	12/2/2023

458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70341	12/2/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70399	12/6/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70409	12/6/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70410	12/6/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70462	12/8/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70493	12/9/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70494	12/9/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70497	12/9/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70501	12/9/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70419	12/12/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70514	12/12/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70523	12/12/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70552	12/13/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70503	12/14/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70605	12/15/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70607	12/15/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70619	12/15/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70636	12/16/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70731	12/21/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70744	12/21/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70760	12/22/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70762	12/22/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70789	12/23/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70833	12/27/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70868	12/28/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70869	12/28/2023
458	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB	70870	12/28/2023
553	MOXIFLOXACIN IN BSS 150MCG/0.1ML SYR	67480	10/9/2023
553	MOXIFLOXACIN IN BSS 150MCG/0.1ML SYR	68640	12/3/2023
553	MOXIFLOXACIN IN BSS 150MCG/0.1ML SYR	68769	12/9/2023
553	MOXIFLOXACIN IN BSS 150MCG/0.1ML SYR	68760	12/10/2023
553	MOXIFLOXACIN IN BSS 150MCG/0.1ML SYR	68925	12/16/2023
553	MOXIFLOXACIN IN BSS 150MCG/0.1ML SYR	70119	1/20/2024
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	67918	10/29/2023
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	68033	11/4/2023
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	68515	11/26/2023
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	68528	11/27/2023
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	68618	12/2/2023
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	68651	12/3/2023
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	68767	12/9/2023
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	68829	12/11/2023
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	69820	1/9/2024
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	70733	2/19/2024
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	71068	3/9/2024
555	CEFUROXIME 10 MG/ML INJ. 0.4 ML SYR	67345	10/3/2023
585	MOXIFLOXACIN IN BSS 100MCG/0.1ML SYR	67623	10/15/2023
585	MOXIFLOXACIN IN BSS 100MCG/0.1ML SYR	67919	10/29/2023
585	MOXIFLOXACIN IN BSS 100MCG/0.1ML SYR	68917	12/16/2023

585	MOXIFLOXACIN IN BSS 100MCG/0.1ML SYR	69079	12/23/2023
585	MOXIFLOXACIN IN BSS 100MCG/0.1ML SYR	69120	12/24/2023
589	LIDO-PHEN 1%-1.5% (1ML) SDV	67849	10/25/2023
589	LIDO-PHEN 1%-1.5% (1ML) SDV	67887	10/28/2023
589	LIDO-PHEN 1%-1.5% (1ML) SDV	68260	11/14/2023
589	LIDO-PHEN 1%-1.5% (1ML) SDV	68534	11/27/2023
589	LIDO-PHEN 1%-1.5% (1ML) SDV	68816	12/12/2023
589	LIDO-PHEN 1%-1.5% (1ML) SDV	69046	12/20/2023
589	LIDO-PHEN 1%-1.5% (1ML) SDV	69971	1/13/2024
608	TPC Drops 1% - 2.5% - 1% 5 mL	68184	10/9/2023
608	TPC Drops 1% - 2.5% - 1% 5 mL	68623	11/2/2023
682	CALCIUM CL 20 MG/ML (500 ML) INJ	70101	1/17/2024
740	LIDOCAINE HCL 4% (3 ML) OPHTH	67443	10/8/2023
740	LIDOCAINE HCL 4% (3 ML) OPHTH	68775	12/9/2023
762	TROPI-PHEN 1% - 2.5% OPHTH SOL (5 ML)	67659	10/16/2023
762	TROPI-PHEN 1% - 2.5% OPHTH SOL (5 ML)	70316	1/30/2024
802	LIDO-OXY NS 2%-0.025% (2 ML) SYR	67808	10/23/2023
959	FOSCARNET 2.4 MG/0.1 ML SYR (0.2 ML)	68680	12/4/2023
963	BEVACIZUMAB 1.25MG/0.05ML INJ - SCLS MN	68890	10/14/2023
963	BEVACIZUMAB 1.25MG/0.05ML INJ - SCLS MN	69012	10/20/2023
963	BEVACIZUMAB 1.25MG/0.05ML INJ - SCLS MN	70093	11/18/2023
963	BEVACIZUMAB 1.25MG/0.05ML INJ - SCLS MN	70275	11/29/2023
963	BEVACIZUMAB 1.25MG/0.05ML INJ - SCLS MN	70259	12/1/2023
963	BEVACIZUMAB 1.25MG/0.05ML INJ - SCLS MN	70299	12/1/2023
963	BEVACIZUMAB 1.25MG/0.05ML INJ - SCLS MN	70406	12/6/2023
963	BEVACIZUMAB 1.25MG/0.05ML INJ - SCLS MN	70450	12/7/2023
963	BEVACIZUMAB 1.25MG/0.05ML INJ - SCLS MN	70613	12/15/2023
987	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ LF	70422	12/9/2023
987	BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ LF	70569	12/14/2023

RECALL ACKNOWLEDGMENT FORM**Product(s):**

(Please list product name as it appears on label)

Lot number(s):

(Please list lot and quantity returned)

Please check ALL appropriate boxes.

- ☐ I have read and understand the recall instructions provided in the October 2nd, 2023 letter.
- ☐ I have checked my stock and have quarantined inventory consisting of _____ units total.
- ☐ I understand product must be returned for credit.

Any adverse events associated with recalled product? ____YES ____NO

➤ ***If yes, please contact quality@pinepharmaceuticals.com.***

Please check the appropriate box(es) to describe your business:

- ☐ Physician Practice
- ☐ Hospital/Medical Facility
- ☐ Hospital Pharmacy
- ☐ Ambulatory Surgery Center
- ☐ Other: _____

Account Number: _____

Facility Name: _____

Tel. number: () _____

Name (Responsible Individual): _____

Title: _____

PLEASE EMAIL COMPLETED RESPONSE FORM TO REGULATORY@PINEPHARMACEUTICALS.COM
OR FAX TO: 716-768-3948 ATTN: REGULATORY
OR MAIL TO: PINE PHARMACEUTICALS 355 RIVERWALK PKWY TONAWANDA, NY 14145