

URGENT PRODUCT RECALL

October 2nd, 2023

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

ITEM 343 - BEVACIZUMAB 1.25 MG/0.05 ML INJ - BD TB

ITEM 987 - BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ LF

ITEM 458 - BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB

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 06/26/2023 and 09/29/2023.

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 repackaged Avastin® intended to be sterile, when produced with specific equipment used in select fill lines.

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 recalled 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 343 - BEVACIZUMAB 1.25 MG/0.05 ML INJ - BD		ITEM 987 - BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ LF			
LOT NUMBER	EXPIRATION DATE	LOT NUMBER	EXPIRATION DATE	LOT NUMBER	EXPIRATION DATE
68620	10/3/2023	68757	10/10/2023	69749	11/7/2023
68632	10/4/2023	68912	10/17/2023	69841	11/8/2023
68789	10/12/2023	69071	10/24/2023	69961	11/14/2023
68822	10/12/2023	69725	10/31/2023	70112	11/21/2023
68914	10/17/2023	69749	11/7/2023	70228	11/28/2023
68952	10/18/2023	69841	11/8/2023	70353	12/5/2023
68954	10/18/2023	69961	11/14/2023	70403	12/9/2023
69105	10/25/2023	70112	11/21/2023	70513	12/12/2023
69731	11/7/2023	70228	11/28/2023	70569	12/14/2023
69991	11/15/2023	70353	12/5/2023	70570	12/14/2023
70142	11/22/2023	70403	12/9/2023	70692	12/20/2023
70233	11/28/2023	70513	12/12/2023	70726	12/21/2023
70258	11/29/2023	70569	12/14/2023	70853	12/27/2023
70297	11/30/2023	70570	12/14/2023	69749	11/7/2023
70355	12/5/2023	70692	12/20/2023	69841	11/8/2023
70404	12/6/2023	70726	12/21/2023		
70516	12/12/2023	70853	12/27/2023		
70579	12/14/2023	68757	10/10/2023		
70659	12/19/2023	68912	10/17/2023		
70664	12/19/2023	69071	10/24/2023		
70700	12/20/2023	69725	10/31/2023		

ITEM 458 - BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB							
LOT NUMBER	EXPIRATION DATE	LOT NUMBER	EXPIRATION DATE	LOT NUMBER	EXPIRATION DATE	LOT NUMBER	EXPIRATION DATE
67538	10/11/2023	68879	10/14/2023	69132	10/28/2023	69928	11/11/2023
68535	10/4/2023	68880	10/14/2023	69142	10/27/2023	69929	11/11/2023
68611	10/3/2023	68886	10/14/2023	69143	10/28/2023	69930	11/11/2023
68612	10/4/2023	68896	10/13/2023	69144	10/28/2023	69931	11/11/2023
68613	10/3/2023	68897	10/13/2023	69166	10/28/2023	69932	11/11/2023
68633	10/4/2023	68913	10/17/2023	69167	10/28/2023	69933	11/11/2023
68634	10/6/2023	68915	10/17/2023	69168	10/28/2023	69962	11/18/2023
68637	10/4/2023	68922	10/18/2023	69169	10/28/2023	69963	11/16/2023
68638	10/5/2023	68923	10/17/2023	69170	10/28/2023	69964	11/14/2023
68673	10/5/2023	68953	10/18/2023	69171	10/28/2023	69965	11/15/2023
68674	10/5/2023	68959	10/20/2023	69726	10/31/2023	69987	11/15/2023
68675	10/5/2023	68976	10/18/2023	69727	10/31/2023	69988	11/15/2023
68699	10/6/2023	68977	10/19/2023	69745	11/4/2023	69990	11/15/2023
68700	10/6/2023	68978	10/19/2023	69746	11/2/2023	69998	11/18/2023
68701	10/6/2023	68979	10/19/2023	69748	11/2/2023	70011	11/18/2023
68702	10/6/2023	68980	10/18/2023	69750	11/2/2023	70031	11/16/2023
68703	10/7/2023	68981	10/19/2023	69751	11/4/2023	70032	11/16/2023
68708	10/7/2023	68982	10/20/2023	69754	11/3/2023	70033	11/16/2023
68709	10/6/2023	69016	10/20/2023	69755	11/3/2023	70034	11/16/2023
68728	10/7/2023	69017	10/20/2023	69768	11/3/2023	70035	11/21/2023
68729	10/7/2023	69018	10/21/2023	69770	11/3/2023	70066	11/17/2023
68736	10/7/2023	69019	10/20/2023	69779	11/4/2023	70067	11/17/2023
68737	10/7/2023	69047	10/21/2023	69780	11/4/2023	70094	11/18/2023
68738	10/7/2023	69048	10/21/2023	69781	11/4/2023	70095	11/18/2023
68739	10/7/2023	69049	10/21/2023	69782	11/4/2023	70113	11/21/2023
68758	10/10/2023	69050	10/21/2023	69783	11/4/2023	70114	11/21/2023
68759	10/10/2023	69051	10/21/2023	69784	11/4/2023	70115	11/21/2023
68784	10/11/2023	69052	10/21/2023	69793	11/4/2023	70116	11/22/2023
68785	10/11/2023	69056	10/21/2023	69794	11/7/2023	70138	11/22/2023
68786	10/11/2023	69072	10/24/2023	69839	11/8/2023	70139	11/22/2023
68787	10/11/2023	69073	10/24/2023	69863	11/9/2023	70140	11/22/2023
68788	10/11/2023	69074	10/24/2023	69864	11/18/2023	70147	11/22/2023
68821	10/12/2023	69075	10/24/2023	69865	11/9/2023	70163	11/23/2023
68823	10/12/2023	69101	10/28/2023	69866	11/9/2023	70164	11/23/2023
68824	10/12/2023	69102	10/25/2023	69867	11/9/2023	70165	11/23/2023
68843	10/13/2023	69103	10/25/2023	69868	11/14/2023	70166	11/23/2023
68844	10/13/2023	69104	10/25/2023	69890	11/10/2023	70167	11/23/2023
68850	10/13/2023	69109	10/25/2023	69892	11/10/2023	70168	11/23/2023
68851	10/13/2023	69127	10/26/2023	69893	11/10/2023	70193	11/24/2023
68852	10/13/2023	69128	10/27/2023	69894	11/10/2023	70194	11/24/2023
68853	10/13/2023	69129	10/26/2023	69895	11/10/2023	70195	11/24/2023
68877	10/14/2023	69130	10/28/2023	69896	11/10/2023	70196	11/24/2023
68878	10/14/2023	69131	10/28/2023	69897	11/10/2023	70197	11/24/2023

ITEM 458 - BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB			
LOT NUMBER	EXPIRATION DATE	LOT NUMBER	EXPIRATION DATE
70198	11/24/2023	70553	12/13/2023
70211	11/25/2023	70571	12/14/2023
70212	11/25/2023	70572	12/14/2023
70213	11/25/2023	70573	12/14/2023
70214	11/25/2023	70585	12/14/2023
70220	11/25/2023	70605	12/15/2023
70229	11/28/2023	70606	12/15/2023
70231	11/28/2023	70608	12/15/2023
70232	11/28/2023	70609	12/15/2023
70234	11/28/2023	70635	12/16/2023
70254	11/29/2023	70636	12/16/2023
70255	11/29/2023	70660	12/19/2023
70256	11/29/2023	70661	12/19/2023
70257	11/29/2023	70662	12/19/2023
70261	11/29/2023	70663	12/19/2023
70262	11/29/2023	70672	12/20/2023
70263	11/29/2023	70693	12/20/2023
70264	11/30/2023	70694	12/20/2023
70265	12/1/2023	70695	12/20/2023
70314	12/1/2023	70696	12/20/2023
70315	12/1/2023	70702	12/20/2023
70324	12/7/2023	70727	12/21/2023
70325	12/2/2023	70728	12/21/2023
70326	12/2/2023	70729	12/21/2023
70339	12/7/2023	70730	12/21/2023
70340	12/15/2023	70731	12/21/2023
70358	12/5/2023	70759	12/22/2023
70397	12/6/2023	70760	12/22/2023
70398	12/6/2023	70762	12/22/2023
70399	12/6/2023	70763	12/22/2023
70445	12/7/2023	70786	12/23/2023
70462	12/8/2023	70787	12/26/2023
70463	12/8/2023	70788	12/23/2023
70465	12/8/2023	70789	12/23/2023
70466	12/8/2023	70790	12/26/2023
70467	12/8/2023	70791	12/23/2023
70494	12/9/2023	70832	1/4/2024
70495	12/9/2023	70835	12/26/2023
70497	12/9/2023	70851	1/4/2024
70523	12/12/2023	70852	12/27/2023
70544	12/13/2023	70860	12/27/2023
70549	12/13/2023	70871	12/28/2023
70552	12/13/2023	70874	12/28/2023

RECALL RETURN RESPONSE FORM**Product(s):**

- ☐ ITEM 343 - BEVACIZUMAB 1.25 MG/0.05 ML INJ - BD TB
- ☐ ITEM 987 - BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ LF
- ☐ ITEM 458 - BEVACIZUMAB 1.25 MG/0.05 ML INJ - NJ TB

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