

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Imprimis NJOF would like to inform you of a recall notice involving Klarity-C (Cyclosporine 0.1%) Sterile Ophthalmic Emulsion. During a recent FDA inspection, investigators observed certain deviations from standard operating procedures regarding the production of Klarity-C (Cyclosporine 0.1%) Sterile Ophthalmic Emulsion.

Imprimis' assessment of this issue revealed the “likelihood of a health hazard is unlikely”, however, out of an abundance of caution, Imprimis NJOF (“Imprimis”) has initiated a recall of all unexpired lots of Klarity-C that reflect observed issues.

To be clear, all the identified lots obtained passing results for sterility, potency, endotoxin testing, identification, minimum fill, finished product pH, and description/color/clarity testing prior to release. Additionally, each lot was fully reviewed and dispositioned by members of the Quality Assurance department prior to release. Furthermore, no adverse drug events were received that directly correlated to the issue at hand.

**Product Name:** Klarity-C (Cyclosporine 0.1%) Sterile Ophthalmic Emulsion

**Description:** Multiuse Sterile Ophthalmic Topical Eyedrops

**NDC:** 71384-514-05

## **Lot Numbers:**

<b>Lot Number</b>	<b>Date Compounded</b>	<b>Expiry Date</b>	<b>Distribution Date Ranges</b>	
23APR005	05/08/23	5/1/2024	7/17/2023	8/4/2023
23MAY024	05/22/23	5/15/2024	6/19/2023	6/19/2023
23JUN010	06/06/23	5/30/2024	8/4/2023	9/27/2023
23JUN016	06/14/23	6/7/2024	9/20/2023	12/19/2023
23JUN047	07/11/23	7/4/2024	8/18/2023	8/18/2023
23JUL013	07/18/23	7/11/2024	9/14/2023	11/29/2023
23JUL029	08/01/23	7/25/2024	10/2/2023	10/2/2023

23JUL030	08/08/23	8/1/2024	10/2/2023	10/2/2023
23AUG016	08/14/23	8/7/2024	10/2/2023	10/2/2023
23AUG042	10/04/23	9/27/2024	11/8/2023	11/8/2023
23SEP017	10/18/23	7/13/2024	12/5/2023	12/5/2023
23OCT039	11/08/23	8/3/2024	12/20/2023	1/24/2024
23NOV022	11/29/23	8/24/2024	1/24/2024	2/16/2024
23NOV036	12/04/23	8/29/2024	1/19/2024	1/19/2024
23DEC021	01/09/24	10/4/2024	2/5/2024	4/16/2024
24JAN018	01/16/24	10/11/2024	4/16/2024	4/16/2024
24JAN026	01/29/24	10/24/2024	2/26/2024	2/26/2024
24JAN040	02/07/24	11/2/2024	4/10/2024	4/16/2024
24FEB021	02/21/24	11/16/2024	3/27/2024	4/18/2024
24MAR005	3/18/2024	12/12/2024	4/16/2024	4/16/2024