

URGENT DRUG RECALL

March 14, 2002

This notice is to inform you that Bayer is initiating a voluntary recall of one lot of Gamimune® N, 10%, Immune Globulin Intravenous (Human), 10%, Solvent/Detergent Treated. This action is being taken with the knowledge of the United States Food and Drug Administration. We are requesting a return of any product from the lot listed below.

<u>Lot Number</u>	<u>Expiration Date</u>	<u>Product Code</u>
648X062	16 July 2004	648-71M 100 mL

This lot was released to the marketplace on 12 September 2001. This voluntary recall is a precautionary measure based on a single customer report received by Bayer describing the presence of a white precipitate in the solution.

Bayer's investigation has revealed that this complaint is similar to that observed for lot number 648X078, Gamimune® N, 10% Immune Globulin Intravenous (Human), 10% Solvent/Detergent Treated recalled by Bayer on 1 February, 2002. In both cases, the overseals of the defective vials were apparently damaged after shipment from Bayer. Bayer's investigation of the damaged vials had identified unexpectedly low protein concentration, elevated chloride and the presence of bacteria.

The recall is required to be conducted to the end user level. The customers should be instructed to return product as indicated below.

If you have further distributed the product, you must send notification of this recall to your customers.

Any vials from the lot listed above are being recalled and should be returned to:

Distribution Supervisor
Bayer Corporation
8368 U.S. 70 West
Clayton, NC 27520

PLEASE RETURN THE POSTCARDS IMMEDIATELY, PROVIDING THE REQUESTED INFORMATION

TO: Ms. Michele Jones
Recall Coordinator
Bayer Corporation
P.O. Box 507
Clayton, NC 27520

You will be credited for your returned goods and the associated shipping charges. If you have any questions regarding returns, please contact Bayer Customer Service at 800-288-8370.

Thank you for your assistance.

Sincerely,



Michael A. Fournel
Vice President
Global Quality Assurance/Compliance

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