GRIFOLS

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URGENT DRUG WITHDRAWAL

November 5, 2019

This is to inform you that Grifols Therapeutics is initiating a voluntary withdrawal of one lot of Gamunex® -C 10%, as detailed below.

As a precautionary measure, this voluntary withdrawal is being conducted due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant. Hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with IVIG products.

This withdrawal is being conducted with the knowledge of the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research.

Gamunex® -C 10%, lot affected by this withdrawal is:

Lot Number	Material Number	Expiration Date	Market Release	NDC Number
A1GLD00622	729688	18 MAY 2022	20 JUN 2019	13533-800-24

The withdrawal is required to be conducted to the consumer /user level. Please notify your subsidiary customers of this withdrawal, and instruct them to return product as noted below.

Please examine your stock immediately to determine if you have any of the above-mentioned lots on hand. If you have product from this lot, cease use of the product immediately. If you have further distributed the product, you must immediately send notification of this withdrawal to your customers. This lot was distributed within the United States only. **Return product to the authorized distributor of record for this lot.** Distributors should return product to Grifols Therapeutics, 8368 US Hwy Bus 70 West, Clayton, NC 27520. For any questions concerning return of the product, contact US Customer Service at (800) 243-4153.

After receipt of returned product by Grifols, you will be credited by your distributor for the returned goods. If you have any technical or clinical questions, please contact US Clinical Communications at (800) 520-2807. Your prompt attention to this notice is appreciated.

Sincerely,

Clark Zervos
Vice President, Quality
Grifols Therapeutics