Gentell®
2701 Bartram Road · Bristol, PA 19007
800-840-9041 · 215-788-2700
FAX 215-788-2715 · www.gentell.com

December 19, 2016

URGENT: DRUG RECALL- NONSTERILE GENTELL HYDROGEL AG, 2x2, 4x4, 4x8, GAUZE AND 4 OZ. TUBES

Dear Valued Customer:

Gentell, Inc. has issued a voluntary recall for the products and lot numbers listed below:

Product Description	Gentell Product Code	Lot Numbers for all Products
Gentell Hydrogel AG 2x2	Gen-11220	1121615, 1121713, 1122215
Gentell Hydrogel AG 4x4	Gen-11460	1123315, 1125215, 1126515,
Gentell Hydrogel AG 4x8	Gen-11860	1127315, 1130015, 1133615
Gentell Hydrogel AG 4 oz. Tube	Gen-11240	1131615, 1136215, 1136415,
		1100616, 1102616, 1105516
		1106216, 1106816, 1108816
		1109616, 1110316, 1111816
		1114116, 1116616, 1118716
		1119516, 1121516, 1123116

Gentell, Inc. is recalling product referenced above due to the amount of active ingredient which cannot be guaranteed. There is also a potential for an allergic reaction to the active ingredient, "Silver Sulfadiazine".

Our records indicate you have received the product that is subject to the recall. We are notifying our customers to take the following actions:

1. If you have the affected stock, discontinue use and quarantine the products listed above that may contain any of the listed lot numbers.

2. To return product, complete the enclosed product "Recall Acknowledgement form" and fax to 215-788-2715 or email to jwebb@gentell.com. A quality representative will contact you with a return goods authorization number (RGA#) and provide instruction for the return of the product(s) to Gentell, Inc.

3. If you have no affected stock, please complete the enclosed "Acknowledgement Form" and fax to 215-788-2715 or email to jwebb@gentell.com,- attention Quality Control.

This will allow us to verify receipt of this letter.

Please be aware that this recall is being executed with the knowledge of the Food and Drug Administration and we appreciate your assistance.

Please know that Gentell, Inc. is committed to providing safe and quality products. Therefore, we apologize for any inconvenience this action may cause your operation. If you have any questions, please do not hesitate to contact me.

Respectfully,

David Navazio,
Executive Vice President