Important Information from Animas Corporation

On December 27, 2011, Animas received a Warning Letter from the U.S. Food & Drug Administration (FDA) following an inspection of our West Chester, Pa. facility that concluded August 10, 2011. Following the receipt of the warning letter, Animas contacted FDA for clarification and confirmed they would like us to provide additional documentation related to some internal quality systems processes and the implementation of design enhancements to improve the durability of our insulin pump keypads.

All components included in our insulin pumps are manufactured according to product specifications. Some patients have experienced gradual deterioration of their insulin pump keypad, resulting in the need for a warranty replacement. We are continuously pursuing opportunities for product improvements, and as we identify those enhancements we implement them into our manufacturing process. We have recently implemented a change in our keypad component to improve durability.

As a separate issue, the FDA letter also requested further clarification around our internal systems for ensuring the prompt reporting of Medical Device Reports. We have implemented corrective actions to improve our processes for reporting all MDRs to FDA in a timely manner.

We are dedicated to quickly resolving the FDA's outstanding concerns and remain strongly committed to manufacturing and delivering products to our customers that meet high quality standards and comply with the regulations of our industry.

We encourage our customers who have any questions or concerns about the Warning Letter to contact our Customer Support Line at **1-855-230-7582**. Thank you.

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