

December 3, 2024

Dear Valued Customer:

To help mitigate drug shortages related to Hurricane Helene, Baxter worked with the U.S. Food and Drug Administration (FDA) to obtain FDA authorization to temporarily import and distribute certain drug products from Baxter's global manufacturing network.

These products are not FDA approved but are authorized by FDA for temporary importation and distribution. FDA does not require any additional approval for the distribution of these products by Baxter or Baxter's authorized distributors, for example an Emergency Use Authorization. Similarly, FDA does not restrict the use of these products following distribution by Baxter or Baxter's authorized distributors.

In general, the temporary importation products are approved in foreign markets and may bear foreign labeling. For each importation product, we provide a Dear Healthcare Provider (DHCP) letter that includes product and labeling differences compared to the equivalent FDA-approved product. In coordination with FDA, the DHCP letters are being distributed electronically, including through posting on Baxter's website. A physical copy of the DHCP is not required to be attached to each distribution of the temporary importation product.

In accordance with FDA's temporary importation authorization, only Baxter and Baxter's authorized agents and U.S. distributors can import and distribute this product. We understand the critical importance of supply continuity and are committed to continuing transparent and proactive communications with you. Regular updates on this situation are posted to Baxter's website at [Hurricane Helene Updates | Baxter](#).

For medical information, support or questions regarding conservation strategies, please contact MedInfo@Baxter.com, call 1-800-933-0303, or visit [Hurricane Helene Conservation and Medical Information Resources | Baxter](#), where you will find a full listing of product codes authorized by FDA for temporary importation.

Thank you for your patience and partnership as we navigate this difficult situation.

Sincerely,

Richard Leber
Senior Manager, Regulatory Affairs, Drug Shortages
Baxter Healthcare Corporation