



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Silver Spring, MD 20993

April 15, 2014

Rick Pollack  
Executive Vice President  
American Hospital Association  
325 Seventh Street, NW, Suite 700  
Washington, DC 20004-2802

Dear Mr. Pollack:

Thank you for your letter of March 20 in which you express the American Hospital Association's concern about the shortage of intravenous (IV) saline and other IV fluids. The Food and Drug Administration (FDA or the Agency) shares your concern and understands that these products are essential to providing patients with the necessary fluids for hydration and for other medical needs.

FDA is aware that there has been an increase in demand for IV saline. Manufacturers of these products have reported that this increase in demand is linked to increased hospital use, which, along with other factors, resulted in a shortage of IV saline in January 2014. As you noted, there are three manufacturers that supply IV saline to U.S. hospitals and health clinics: Baxter Healthcare Corp., B. Braun Medical Inc., and Hospira Inc. A fourth manufacturer, Fresenius Medical Care, supplies IV saline to dialysis centers. All four companies are working to restore the supply of IV saline and other IV solutions. More information can be found on FDA's Drug Shortages website, <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>.

The Agency is actively pursuing options to secure additional supplies as soon as possible in order to meet the needs of patients during the shortage. In light of the current situation, FDA obtained information from Fresenius Kabi USA, LLC, based in Lake Zurich, Illinois, about the 0.9 percent sodium chloride injection made in its Norway facility, and conducted an inspection to ensure that the facility meets FDA standards. Based on the Agency's review, and while the drug is needed to address the critical shortage of IV saline, FDA is temporarily exercising enforcement discretion for the distribution of 0.9 percent sodium chloride injection from Fresenius Kabi USA's Norway facility. FDA asks that health care providers contact Fresenius Kabi USA directly to obtain the product.

FDA remains committed to preventing shortages and minimizing the impact of this issue by using all of the regulatory tools at its disposal so that patients can obtain the medications that they need. On October 31, 2013, the Agency issued its *Strategic Plan for Preventing and Mitigating Drug Shortages*.<sup>1</sup> The plan contains details on the origin of drug shortages, FDA's processes and procedures for helping to prevent or mitigate these shortages, and FDA's strategy for strengthening those processes and procedures. It also outlines recommendations for actions other stakeholders may consider to help prevent drug shortages.

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<sup>1</sup> To view the Strategic Plan and related information, visit <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf>

Mitigation efforts begin once FDA has confirmed that a shortage exists or could occur. To prevent or mitigate a shortage, FDA can, as appropriate:

- Identify the extent of the shortfall and determine if other manufacturers are willing and able to increase production to make up the gap;
- Expedite FDA inspections and reviews of submissions from manufacturers attempting to restore production;
- Expedite FDA inspections and reviews of submissions from competing manufacturers who are interested in starting new production or increasing existing production of products in shortage;
- Exercise temporary enforcement discretion for new sources of medically necessary drugs;
- Work with the affected manufacturers to ensure adequate investigation into the root cause of the shortage; and
- Develop risk mitigation measures for a batch or batches of product initially not meeting established standards.

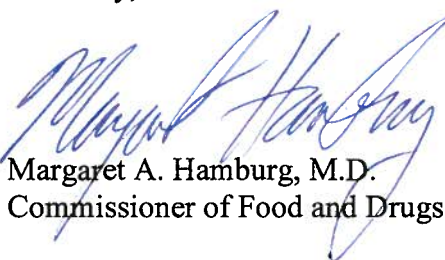
FDA does not have the authority to require a manufacturer to make a product or to direct a manufacturer's business decisions about manufacturing capacity. However, the Agency will continue to provide expedited regulatory review and advice to manufacturers of IV saline and other drugs most in need. FDA will also continue working with Baxter Healthcare Corp., B.Braun Medical Inc., Hospira Inc., and Fresenius Medical Care to help preserve the supply of IV saline in U.S. hospitals and health clinics.

As outlined in the October 31, 2013, Strategic Plan, and considering that the majority of drug shortages are the result of production disruptions caused by manufacturing problems related to quality, FDA is exploring what it can do to provide more positive incentives for quality improvements and to make manufacturing quality a priority. Having a better understanding of the factors contributing to supply disruptions and drug shortages, and identifying potential warning signals of future production disruptions, could help FDA and manufacturers in their efforts to prevent supply disruptions and drug shortages.

Please be assured that the prevention and mitigation of drug shortages is a key priority for FDA. The Agency will take every action within its authority to help alleviate the shortage of IV saline and other drugs and increase supplies in the marketplace. FDA will continue to work with manufacturers, providers, patients, patient advocates, and other stakeholders to protect patients and identify solutions to this serious problem.

Thank you for contacting me regarding this important matter. Please let me know if you have further thoughts or concerns.

Sincerely,



Margaret A. Hamburg, M.D.  
Commissioner of Food and Drugs