



John Ducker
President and CEO
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, Illinois 60047

Dear Mr. Ducker:

The U.S. Food and Drug Administration (FDA) is pleased to announce that Fresenius Kabi USA, LLC has been selected to receive a Drug Shortage Assistance Award for its role in preventing or alleviating a drug shortage.

Fresenius Kabi is being recognized for its efforts related to mitigating the shortage of IV saline, including temporary importation of their product and ultimately submitting and obtaining approval of an abbreviated new drug application (207310) for Sodium Chloride Injection USP, 0.9%, adding additional approved supplies to the U.S. market.

FDA established this award program to recognize companies for making a substantial contribution to preventing or alleviating a drug shortage. FDA hopes this award serves as an incentive for other companies to assist in addressing drug shortages, as Fresenius Kabi has done.

The intent of the award program is to recognize manufacturers or companies that assist FDA in addressing a drug shortage, for their commitment to public health and -quality manufacturing, a key component of the Strategic Plan for Preventing and Mitigating Drug Shortages. More information on the strategic plan can be found on FDA's drug shortages web page (<http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm>).

FDA thanks Fresenius Kabi for working to mitigate the shortage of Sodium Chloride Injection USP, 0.9%. The enclosed press release/web statement template is provided to assist you in publicizing your award from FDA.

Sincerely,

Douglas C. Throckmorton, M.D.
Deputy Center Director for Regulatory Programs,
FDA, Center for Drug Evaluation and Research

Enclosure(s):
Certificate
Optional Press Release/Web Statement Template

cc: Fresenius Kabi USA, LLC