

November 8, 2023

Dr. Vishy Chebrol CEO, Sagent Pharmaceuticals 1901 N. Roselle Road, Suite 450 Schaumburg, IL 60195 vchebrol@sagentpharma.com

Dear Dr. Chebrol,

The U.S. Food and Drug Administration (FDA or the Agency) is pleased to announce that Sagent Pharmaceuticals (Sagent) has been selected to receive a Drug Shortage Assistance Award for its role in preventing or alleviating a drug shortage.

Sagent is being recognized for its efforts related to the prevention of several critical potential shortages. Per Drug Shortage Staff procedures, Sagent was contacted for supply assistance with six critical injectable products, due to potential market shortfalls. Sagent reported substantial inventory levels and ability to monitor the market and/or work with the application holder(s) to obtain more inventory if necessary for each of these products and therefore, was able to assist immediately and help prevent a shortage.

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 Sagent 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 Sagent for helping to mitigate shortages of these critical products. The enclosed press release/web statement template is provided to assist you in publicizing your award from FDA.

Sincerely,

Douglas C. Throckmorton MD

Douglas 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: James Horger, Vice President, Quality and Regulatory Compliance, Sagent Susan Lewis, Vice President, Regulatory Affairs, USA