DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

April 14, 2016

Riad Mishlawi, EU Vice President and Global Head of Injectables
Eurohealth International Sàrl, a subsidiary of Hikma Pharmaceuticals
Estrada do Rio da Mó, 8, 8A e 8B - Fervença
Sintra, Portugal
2705-906

Dear Mr. Mishlawi:

The U.S. Food and Drug Administration (FDA) is pleased to announce that Eurohealth, a subsidiary of Hikma Pharmaceuticals (Eurohealth) has been selected to receive a Drug Shortage Assistance Award for its role in preventing or alleviating drug shortages.

Eurohealth is being recognized for its efforts related to the shortages of thiotepa for injection and phentolamine mesylate for injection, including acquiring the new drug applications and submitting post-approval supplements to restart manufacturing with acceptable compliance records.

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 Eurohealth has.

The intent of the award program is to bring attention to manufacturers or companies that assist in addressing a drug shortage and prioritize 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 Eurohealth for working to alleviate the shortages of thiotepa and phentolamine mesylate for injections. 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:
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