



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Silver Spring, MD 20993

September 18, 2014

Peter George, Group Chief Executive Officer  
Clinigen Group plc  
Pitcairn House, Crown Square, Centrum 100  
Burton-on-Trent  
DE14 2WW

Dear Mr. George:

The U.S. Food and Drug Administration (FDA or the Agency) is pleased to announce that Clinigen Group plc is one of two drug companies selected to receive a Drug Shortage Assistance Award for its role in preventing or alleviating a drug shortage.

Clinigen is being recognized for its efforts related to the shortage of Foscavir (foscarnet sodium) injection, including acquiring the new drug application and submitting post-approval supplements to restart manufacturing with acceptable compliance records.

FDA recently 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 Clinigen 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 Clinigen for working to alleviate the shortage of Foscavir. The enclosed press release/web statement template is provided to assist you in publicizing your award from FDA.

Sincerely,

/s/

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

Enclosures:  
Certificate  
Optional Press Release/Web Statement Template

cc: Jason Shelley, Head of Quality/Responsible Person, Clinigen Group  
John JF Killackey, Ph.D., Director, Regulatory Affairs, USA, OptumInsight