



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Silver Spring, MD 20993

September 18, 2014

Dr. Yves L'Epine, Chief Executive Officer  
Guerbet Group  
15 Rue des Vanesses  
Zone Paris Nord II  
93420 Villepinte  
France

Dear Dr. L'Epine:

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

Guerbet is being recognized for its efforts related to the shortage of Ethiodol (ethiodized oil) injection, currently approved as Lipiodol, including acquiring the new drug application, submitting several post-approval supplements to restart manufacturing with acceptable compliance records, and gaining further approval to market the product for a well-known and medically necessary indication in the United States.

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 Guerbet 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 Guerbet for working to alleviate the shortage of Ethiodol. 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: Corina Harper, Director, North America Medical and Regulatory Affairs, Guerbet LLC