DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-818

Sun Pharma Global, FZE
Attention: Anne Toland
Director, Regulatory Affairs
2064 State Road, Suite 103
Bensalem, PA 19020

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) for Oxaliplatin for Injection, (Preservative-Free), packaged in 50 mg and 100 mg Single-use Vials, which was submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), and approved on August 7, 2009.

The Food and Drug Administration (FDA) is hereby notifying you that approval of this ANDA is suspended in accordance with the order issued on August 13, 2009 by the United States Court of Appeals for the District of Columbia Circuit. Approval of this ANDA will not become effective until FDA issues a letter lifting the suspension of approval, which is dependant on further order of the court.

Please note that, pursuant to section 505(a) of the Act, no person "shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of the application filed pursuant to subsection 505(b) or (j) [of the Act] is effective with respect to such drug." Also, until the approval is no longer suspended, this drug product will not be listed in the "Orange Book".

If you have any questions regarding this letter, please contact Cecelia M. Parise, R.Ph., Regulatory Policy Advisor to the Director, Office of Generic Drugs at 240-276-9310.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST
08/14/2009
Deputy Director, for Gary Buehler