CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-160

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-160

NDA APPROVAL

Teva Parenteral Medicines, Inc.
Attention: Susan O'Brien
Director, Regulatory Affairs
19 Hughes
Irvine, CA 92618-1902

Dear Ms. O'Brien:

Please refer to your new drug application (NDA) dated February 9, 2007, received February 9, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Oxaliplatin Injection, 50 mg/10 mL and 100 mg/20 mL.

Reference is also made to our letter dated August 14, 2009, notifying you that the Agency suspended approval of this NDA in accordance with the order issued on August 13, 2009 by the United States Court of Appeals for the District of Columbia Circuit.

This letter is to inform you that pursuant to the order of the United States Court of Appeals for the District of Columbia Circuit (1:09-CV-01495-EGS) filed on August 18, 2009 dissolving the court's August 13, 2009 administrative injunction, the approval of the referenced NDA is no longer suspended. The conditions of approval of this NDA communicated to you in the original approval letter dated August 7, 2009 are in effect.

If you have any questions, call Amy Tilley, Regulatory Project Manager, at 301-796-3994

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: Labeling

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 JUSTICE
08/19/2009