DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 101063/5071

JUL 21 2006

Ovation Pharmaceuticals, LLC
Attention: Jane Stachura, M.S.
Director, Global Regulatory Affairs
Four Parkway North, Suite 200
Deerfield, IL 60015

Dear Ms. Stachura:

Your request to supplement your biologics license application for Asparaginase to revise the ADVERSE REACTIONS section of the package insert to add information on pancreatitis, cerebral vascular events, hepatic failure, depletion of plasma levels of protein C, S, and antithrombin III, and seizures has been approved.

We acknowledge your written agreement, as stated in your letter of July 13, 2006, to do the following:

- To voluntarily submit by September 30, 2006, a prior-approval labeling supplement to convert the current package insert to the new Physician's Labeling Rule (PLR) format.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. The final printed labeling (FPL) must be identical to the enclosed labeling text dated July 13, 2006. Marketing product with FPL that is not identical to the approved labeling may render the product misbranded and an unapproved drug. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text dated July 13, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

Please refer to http://www.fda.gov/cder/biologics/default.htm for important information regarding therapeutic biological products, including the addresses for submissions.

Effective August 29, 2005, the new address for all submissions to this application is:

Food and Drug Administration
Center for Drug Evaluation and Research
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

This information will be included in your biologics license application file.

Sincerely,

Patricia Keegan

Patricia Keegan, M.D.
Director
Division of Biologic Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research