DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 101063/5081

MAR 3 0 2007

Ovation Pharmaceuticals, Incorporated
Attention: Jane M. Stachura, M.S.
Director, CMC and 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 your current physician package insert to conform to the new labeling content and format requirements in 21 CFR 201.56(d) and 201.57, has been approved.

We acknowledge your written commitment to provide additional information as described in your letter of March 29, 2007, as outlined below:

Postmarketing Study Commitment subject to reporting requirements of 21 CFR 601.70.

To submit by November 1, 2007, a labeling supplement to update the label with data acquired from the Children's Oncology Group (COG). Specifically, Ovation Pharmaceuticals, Incorporated, will:

- Obtain and summarize data for a revised PK/PD section of the label.
- Obtain and summarize adverse reactions data pertaining to anaphylaxis and provide the incidence of events of anaphylaxis in the 11 clinical trials and the number of deaths due to anaphylaxis in those trials.

We request that you submit your final study report (labeling supplement) to this biologics license application (BLA), STN BL 101063. Please use the following designators to label prominently all submissions, including the labeling supplement, relating to this postmarketing study commitment as appropriate:

- Postmarketing Study Commitment - Final Report
- Postmarketing Study Correspondence
- Annual Status Report of Postmarketing Study Commitments

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. The status report for each study should include:

- information to identify and describe the postmarketing commitment,
- the original schedule for the commitment,
- the status of the commitment (i.e. pending, ongoing, delayed, terminated, or submitted),
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e. number enrolled to date and the total planned enrollment), and
- a revised schedule if the study schedule has changed and an explanation of the basis for the revision.

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our Web site (http://www.fda.gov/cder/pmc/default.htm). Please refer to the February 2006 Guidance for Industry: Reports on the Status of Postmarketing Study Commitments - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (see http://www.fda.gov/cder/guidance/5569fnl.htm) for further information.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please submit within 30 days 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 March 30, 2007. 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 information regarding therapeutic biological products, including the addresses for submissions.

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

Enclosure: Package Insert