CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-303

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-303

NDA APPROVAL

Cephalon, Inc.
Attention: Carol S. Marchione
41 Moores Road, P.O. Box 4011
Frazer, PA 19355

Dear Ms. Marchione:

Please refer to your new drug application (NDA) dated December 28, 2007, received December 31, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Treanda® (bendamustine hydrochloride) Injection.

We acknowledge receipt of your submissions dated January 17, February 4, March 6, April 23, April 29, May 5, May 14, July 17, July 28, September 5, October 6, October 9,October 24 (3), October 27 (3), October 28 (3), October 29 (2), and October 30 (3).

This new drug application provides for the use of Treanda for indolent B-cell non-Hodgkins lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (test for package insert) submitted October 30, 2009. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-303."

We acknowledge your October 30, 2008 submission containing final printed carton and container labels.

PEDIATRIC RESEARCH EQUITY ACT (PREA)

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Milinda Vialpando, Regulatory Project Manager, at (301) 796-1444.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Robert Justice
10/31/2008 02:52:26 PM