DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021248/S-008/S-009 **SUPPLEMENT APPROVAL**

Cephalon Inc.
Attention: Franklin Vairinhos, Ph.D.
41 Moores Road,
P.O. Box 4011
Frazer, PA 19355

Dear Dr. Vairinhos:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trisenox (arsenic trioxide for injection).

Supplement	Letter date	Received date	Provides for	Your Amendments
021248/S-008	December 19, 2008	December 22, 2008	Updating the Adverse Reactions section of the package insert to Include information on post marketing experience (CBE)	August 19, 2009 April 29, 2010 June 9, 2010
021248/S-009	January 9, 2009	January 13, 2009	Updating Clinical Pharmacology and Precautions sections of the package insert (PAS)	April 13, 2010 April 29, 2010 June 9, 2010

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

POSTMARKETING COMMITMENT—FULFILLED

We have received your submission dated April 13, 2010, reporting on the following postmarketing commitment.

1162-7 Analyze data from all the pharmacokinetic studies conducted as a Phase 4 commitment to evaluate the influence of age, gender, and race on the pharmacokinetics of arsenic trioxide.

As you agreed in your August 18, 2000, submission, you will stratify patients according to age, gender, and race for whom pharmacokinetic data are available from the studies conducted for the Phase 4 commitment in an attempt to evaluate the influence of age, gender, and race on the pharmacokinetics of arsenic trioxide.

We have reviewed your submission and conclude that the above commitment was fulfilled.

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our September 25, 2000, letter.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing,

Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
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 Alberta Davis-Warren, Regulatory Project Manager, at (301) 796-3908.

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, M.D.
Acting Director
Division of Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21248	SUPPL-9	CEPHALON INC	TRISENOX
NDA-21248	SUPPL-8	CEPHALON INC	TRISENOX
NDA-21248	PMR/PMC-1	CEPHALON INC	TRISENOX

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

/s/

ANN T FARRELL
07/23/2010