DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020717 / S-040 and 041
NDA 021875 / S-016 and 017

SUPPLEMENT APPROVAL
REMS ASSESSMENT ACKNOWLEDGEMENT
RELEASE REMS REQUIREMENT

Cephalon, Inc.
Attention: Paul Kirsch
Senior Director and Group Leader
Regulatory Affairs
PO Box 4011
41 Moores Road
Frazer, PA 19355

Dear Mr. Kirsch:

Please refer to your Supplemental New Drug Applications (sNDAs) dated October 20, 2011 and January 9, 2012, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Provigil (modafinil) tablets and Nuvigil (armodafinil) tablets.

sNDAs 020717/S-0040and 021875/S-016 contain an assessment of the risk evaluation and mitigation strategy (REMS) for Provigil (modafinil) and Nuvigil (armodafinil). After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be complete.

sNDAs 020717/S-0041 and 021875/S-017 are Prior Approval supplemental new drug applications that propose to eliminate the requirement for the approved Provigil (modafinil) and Nuvigil (armodafinil) REMS. We have completed our review of these supplemental applications and they are approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Provigil (modafinil) and Nuvigil (armodafinil) were originally approved on October 21, 2010. The REMS consist of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Provigil (modafinil) and Nuvigil (armodafinil).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an

element of the approved REMS to ensure that the benefits of Provigil (modafinil) and Nuvigil (armodafinil) outweigh their risks.

The REMS assessment submitted on October 20, 2011 demonstrated that the key components of the communication plan (the distribution of Dear Healthcare Professional letters, Prescriber Brochures, and Pharmacist Action letters following REMS approval) have been completed. Although the assessment suggested that understanding of the risk of serious skin reactions by physicians is not optimal, we have determined that the risk of serious skin reactions is likely to be lower than expected at the time of the drugs' approval, and it is no longer necessary to include the communication plan as an element of the approved REMS to ensure that the benefits of the Provigil and Nuvigil outweigh the risks.

Therefore, we agree with your proposal to eliminate the REMS for Provigil (modafinil) and Nuvigil (armodafinil).

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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 Susan Daugherty, Regulatory Project Manager, at (301) 796-0878.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

RUSSELL G KATZ
01/13/2012