DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-717/S-009

Cephalon, Inc.
Attention: Paul Kirsch
Senior Director, Regulatory Affairs
145 Brandywine Parkway
West Chester, PA 19380-4245

Dear Mr. Kirsch:

Please refer to your Supplemental New Drug Application submitted on March 28, 2003, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Provigil® (modafinil) Tablets.

This supplement provides for a new formulation of the drug product, manufacturing changes, and the addition of a new site, (b)(4)-------- for manufacturing, testing, packaging and labeling of the reformulated drug product.-

We acknowledge receipt of your amendments dated June 13, 17 and 18, 2003.

We have completed our review of this supplement and the application is approved.

We also wish to forward the following additional advice for future submissions:

1. Please note that the dissolution test should only use one tablet per vessel rather than (b)(to allow for the evaluation of the quality of each tablet.

2. In the future, the highest tablet strength, rather than the highest dose, should be used in bioequivalence studies.

If you should have any questions, please call Ms. Anna Marie H. Weikel, Senior Regulatory Health Project Manager, at (301) 594-5535.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug 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/

Thomas Laughren
7/29/03 07:54:02 AM
Signed for Russell Katz, M.D.