DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-717/S-006

Cephalon, Inc.
Attention: Kenneth L. White, Pharm.D.
Vice President, Regulatory Affairs
145 Brandywine Parkway
West Chester, PA 19380-4245

Dear Dr. White:

Please refer to your supplemental new drug application dated March 21,2003, received March 24,2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Provigil (modafinil), 100 and 200 mg tablets.

We acknowledge receipt of your submission dated March 21, 2003.

Your submission of March 21, 2003 constituted a complete response to our February 21, 2003 action letter.

This supplemental new drug application provides for revision of the blister unit and carton labeling.

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

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels submitted March 21, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20717/s-006." Approval of this submission by FDA is not required before the labeling is used.

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

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Anna Homonnay, Regulatory Project Manager, at (301) 594-5535.

Sincerely,

{See appended electronic signature page}

Maryla Guzewska, Ph.D.
Chemistry Team Leader, Neurology Drugs for the
Division of Neuropharmacological Drug Products,
(HFD-120)
DNDC I, Office of New Drug Chemistry
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/

Maryla Guzewska

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