CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-717/S-001

Name:	Provigil Tablets
Generic Name:	modafinil
Sponsor:	Cephalon, Inc.
Approval Date:	12/14/99

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-717/S-001

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EA/FONSI	
Pharmacology Review(s)	
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APPLICATION NUMBER:

NDA 20-717/S-001

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-717/S-001

Cephalon, Inc.
Attention: Paul M Kirsch
Director, U.S. Regulatory Operations
145 Brandywine Parkway
West Chester, PA 19380-4245

Dear Mr. Kirsch:

Please refer to your supplemental new drug application dated November 16, 1999, received November 17, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Provigil® (modafinil) Tablets.

The supplemental application provides for revision of the specification for[ ] (magnesium silicate) used in the manufacture of Provigil Tablets by widening the limits for Loss on Drying (LOD) and Loss on Ignition (LOI).

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Anna Marie Homonnay-Weikel, R.Ph., Project Manager, at (301) 594-5535.

Sincerely,

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

cc:
Archival NDA 20-717
HFD-120/division file
HFD-120/A.Hommonay-Weikel
HFD-120/M.Guzewska
HFD-120/M.Heimann
HFD-095/DDMS-IMT
HFD-810/DNDC Division Director/J.Simmons
DISTRICT OFFICE

Drafted by: MRH/December 13, 1999
Initialed by: M.Guzewska
Final: MRH/12/14/99

filename: D:\WORD#WP\#NDA\N20-717\S20717_001_LET.DOC

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-717/S-001

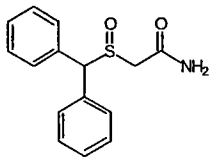
CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW OF SUPPLEMENT

ORGANIZATION:	**HFD-120**
NDA NUMBER:	**20-717**
SUPPLEMENT NUMBER:	**SCS-001**
LETTER DATE	16-NOV-1999
STAMP DATE	17-NOV-1999
AMENDMENTS/REPORTS:	
LETTER DATE	N/A
STAMP DATE	N/A
RECEIVED BY CHEMIST:	23-NOV-1999

Applicant Name and Address: Cephalon, Inc.
145 Brandywine Parkway
West Chester, PA 19380-4245

NAME OF DRUG:	**PROVIGIL®**
NONPROPRIETARY NAME:	Modafinil
CHEMICAL NAME / STRUCTURE:	2-[(Diphenylmethyl)sulfinyl]acetamide
DOSAGE FORM(S):	Tablet
POTENCY(IES):	100 mg, 200 mg
PHARMACOLOGICAL CATEGORY:	Narcolepsy
HOW DISPENSED:	XX (Rx) ___ (OTC)
RECORDS / REPORTS CURRENT:	XX (YES) ___ (NO)
RELATED IND / NDA / DMF(S):	N/A



SUPPLEMENT PROVIDES FOR: revision of the specification for [redacted] (magnesium silicate) used in the manufacture of Provigil Tablets by widening the limits for Loss on Drying (LOD) and Loss on Ignition (LOI).

COMMENTS: [redacted]

[redacted] The type of supporting data required was discussed in a telecon with the sponsor on 16-SEP-99. All of the supporting information that we requested has been provided in this submission. [Refer to review notes.]

CONCLUSIONS AND RECOMMENDATIONS:

Recommend Approval of S-001.

Martha R. Heimann, Ph.D., Review Chemist

cc: Orig. NDA 20-717
HFD-120/Division File
HFD-120/AHommonay-Weikel
HFD-120/MGuzewska/Init.by: MG/
HFD-120/MHeimann

Filename: D:\WORD#WP\#NDA\N20-717\S20717_001.DOC

Review Completed: 14-DEC-1999

Redacted 2 page(s)

of trade secret and/or

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information from

S-001. Chemistry Review