CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-717/S-003

Name:	Provigil Tablets
Generic Name:	modafinil
Sponsor:	Cephalon, Inc.
Approval Date:	09/19/00

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-717/S-003

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EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-717/S-003

APPROVAL LETTER

SEP 19 2000

NDA 20-717/S-003

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 August 15, 2000, received August 16, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROVIGIL® (modafinil) Tablets 100 mg and 200 mg.

We acknowledge receipt of your submission dated August 15, 2000, received September 15, 2000.

This "Changes Being Effected" supplemental new drug application provides for a revision of the specifications and procedures for the drug product, Provigil.

We have completed the review of this supplemental new drug application, as amended, 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, call Anna Marie Homonnay, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely,

9/19/00

Maryla Guzewska, Ph.D.
Chemistry Team Leader, Neurology Drugs for the Division
of Neuropharmocological Drug Products, (HFD-120)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:
Archival NDA 20-717
HFD-120/Div. Files
HFD-120/AMHommonay
HFD-120/DJCummings 9/19/2000
HFD-120/MGuzewska
HFD-120/MHeimann
HFD-095/DDMS-IMT
HFD-810/JSimmons
DISTRICT OFFICE

Drafted by: DJC/September 19, 2000
Initialed by:
Final:
Filename: N20717S3.APL
APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

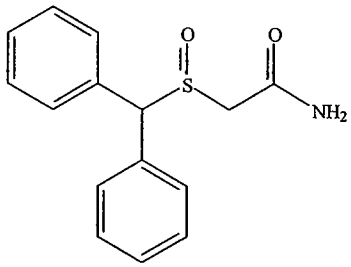
NDA 20-717/S-003

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW OF SUPPLEMENT

ORGANIZATION:	**HFD-120**
NDA NUMBER:	**20-717**
SUPPLEMENT NUMBER:	**SCS-003**
LETTER DATE	15-AUG-00
STAMP DATE	16-AUG-00
AMENDMENTS/REPORTS:	
LETTER DATE	15-AUG-00
STAMP DATE	15-SEP-00
RECEIVED BY CHEMIST:	06-SEP-00

APPLICANT NAME AND ADDRESS: CEPHALON
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 (oral)
POTENCY(IES): 100 mg and 200 mg
PHARMACOLOGICAL CATEGORY: To improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy.
HOW DISPENSED: **XX (Rx)**
RECORDS / REPORTS CURRENT: **XX (YES)**
RELATED IND / NDA / DMF(S): N/A

SUPPLEMENT PROVIDES FOR: Revision of the specifications and procedures for the drug product, Provigil (CBE-30).

COMMENTS: The firm provides copies of the revised specifications and methods (release and stability) for the 100 mg and 200 mg tablets. The references to USP 23 are changed to USP 24. The firm has implemented other minor changes. A copy of the revised cover letter is provided in Attachment 1.

CONCLUSIONS AND RECOMMENDATIONS: APPROVAL

REVIEWER NAME	SIGNATURE	DATE COMPLETED
David J. Cummings		September 19, 2000

cc: Orig.; NDA 20-717
HFD-120/Div. File
HFD-120/AHommonay
HFD-120/DJCummings
HFD-120/MHeimann
INIT: MGuzewska/

Filename: N20717S3

Redacted 6 page(s)

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confidential commercial

information from

5-003. Chemistry Review