CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-717/S-002

Name: Provigil Tablets

Generic Name: modafinil

Sponsor: Cephalon, Inc.

Approval Date: 5/17/00
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### Reviews / Information Included in this Review

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APPLICATION NUMBER:
NDA 20-717/S-002

APPROVAL LETTER
NDA 20-717/S-002

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 April 4, 2000, received April 5, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Provigil® (modafinil) Tablets.

This "Changes Being Effect" supplemental new drug application provides for revision of the specifications for modafinil drug substance, Provigil tablet and Provigil Tablets. The changes are in the procedures used by the contract manufacturer, .

. A requirement to determine the chromatographic tailing factor for the modafinil peak during HPLC analysis is also added.

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, call Anna Marie Homonnay, R.Ph., Project Manager, at (301) 594-2850.

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
NDA 20-717/S-002
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cc:
Archival NDA 20-717
HFD-120/Div. Files
HFD-120/A.Homonnay
HFD-120/M.Guzewska
HFD-120/M.Heimann
HFD-095/DDMS-IMT
HFD-810/J.Simmons
DISTRICT OFFICE

Drafted by: mrb/May 17, 2000
Initialed by:
final: 5/17/2000
filename: D:\WORD#WP\NDA\N20-717\S20717_002_LET.DOC

APPROVAL (AP)
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-717/S-002

CHEMISTRY REVIEW(S)
CHEMIST'S REVIEW
OF SUPPLEMENT

ORGANIZATION: HFD-120
NDA NUMBER: 20-717
SUPPLEMENT NUMBER: SCM-002
LETTER DATE 04-APR-2000
STAMP DATE 05-APR-2000
AMENDMENTS/REPORTS:
LETTER DATE N/A
STAMP DATE N/A
RECEIVED BY CHEMIST: 13-APR-2000

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 specifications for modafinil drug substance, Provigil tablet and Provigil Tablets. The changes are in the procedures used by the contract manufacturer, A requirement to determine the chromatographic tailing factor for the modafinil peak during HPLC analysis is also added.

COMMENTS: The changes below apply to all HPLC procedures for analysis of bulk drug substance (assay/related substances), the and finished tablets (assay/related substances and) except as noted.

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/AHommongay
HFD-120/MGuzewska/Init.by: MG/
HFD-120/MHeimann
Filename: D:WORD#WP#NDA\20-717\S20717_002.DOC
Review Completed: 17-MAY-2000