

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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**APPLICATION NUMBER:
NDA 20-717/S-002**

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Reviews / Information Included in this Review

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EA/FONSI	
Pharmacology Review(s)	
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Microbiology Review(s)	
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APPLICATION NUMBER:
NDA 20-717/S-002

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

M Heimann

Food and Drug Administration
Rockville MD 20857

NDA 20-717/S-002

MAY 17 2000

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 Effected" 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,

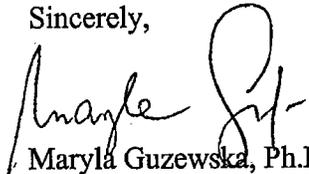
. A requirement to determine the chromatographic tailing factor for the modafinil peak during HPLC analysis is also added.

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,



5/17/00

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

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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: mrh/May 17, 2000

Initialed by:

final: 5/17/2000

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APPROVAL (AP)

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APPLICATION NUMBER:
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CHEMISTRY REVIEW(S)

