CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020717

Trade Name: PROVIGIL TABLETS

Generic Name: MODAFINIL

Sponsor: CEPHALON, INC

Approval Date: 12/24/98

INDICATION(s): TREATMENT OF NARCOLEPSY

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	Included	Pending Completion	Not Prepared	Not Required
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Chemistry Review(s)	X			
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Pharmacology Review(s)	X			
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Clinical Pharmacology Biopharmaceutics Review(s)	X			
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APPROVAL LETTER

NDA 20-717

Cephalon, Inc.
Attention: Kenneth White, Pharm D
145 Brandywine Parkway
West Chester, PA 19380-4245

Dear Dr. White:

Please refer to your new drug application (NDA) dated December 27, 1996, received December 30, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROVIGIL (modafinil) Tablets.

We acknowledge receipt of your submissions dated March 30, May 6, June 4 and 30, July 27, October 9 and 30, November 11, and December 14 and 16, 1998.

This new drug application provides for the use of PROVIGIL (modafinil) Tablets for narcolepsy.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 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 NDA 20-717." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitments specified in your submissions dated March 30, and December 16, 1998. These commitments, along with any completion dates agreed upon, are listed below:

(b)(4)(CC)----------

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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 M. Homonnay-Weikel, R.Ph., Project Manager, at (301) 594-5535.

Sincerely,

/S/ [redacted]

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure