

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:

NDA 20-717
Page 3

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,

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

Enclosure