

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

**Application Number: 16832/S016**

**Trade Name: CYLERT TABLETS**

**Generic Name: PEMOLINE**

**Sponsor: ABBOTT LABORATORIES**

**Approval Date: 5/8/98**

**Indication(s): TREATMENT OF ATTENTION DEFICIT  
DISORDER**

# CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION: 16832/S016**

## CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tentative Approval Letter				X
Approvable Letter				X
Final Printed Labeling				X
Medical Review(s)				X
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				X
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)				X
Administrative Document(s)/ Correspondence				X

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number: 16832/S016**

**APPROVAL LETTER**

NDA 16-832/S-016

Abbott Laboratories  
Pharmaceutical Products Division  
Attention: James D. Steck  
100 Abbott Park Road  
Abbott Park, IL 60064-3500

MAY 8 1998

Dear Mr. Steck:

Please refer to your supplemental new drug application dated November 25, 1997, received November 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cylert® (pemoline) Tablets, 18.75mg, 37.5mg, and 75mg.

We also acknowledge receipt of your additional communications dated December 5, 1997 and February 10, 1998 amending this supplemental application.

The User Fee goal date for this application is May 26, 1998.

The supplemental application provides for a new closure design

Cylert® Tablets. Data and information for the following caps and bottles for Cylert® Tablets

following statement is added to the label bottle opening is broken or missing".

APPEARS THIS WAY  
ON ORIGINAL

"Sealed for Your Protection". Also, the  
"Do not accept if seal over

We note that the stability testing should be initiated on the first production batch of Cylert® Tablets based on the approved protocol for selection of batches of different strengths and packaging sizes and configurations. The stability study results should be reported to the Agency in annual reports.

We have completed the review of this supplemental 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, please contact Anna Marie Homonnay, R.Ph., Project Manager, at (301) 594-5535.

Sincerely yours,

/S/

Maryla Guzewska, Ph.D.  
Chemistry Team Leader DNDC-I  
Division of Neuropharmacological Drug  
Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

APPEARS THIS WAY  
ON ORIGINAL

cc: NDA 16-832/S-016  
HFD-120/Division Files  
HFD-AMHomonnay  
HFD-120/DKlein /S/ 5/1/98  
/MGuzewska 5.8.98  
HFD-810/JSimmons  
HFD-92/DDM/DIAB  
HFR-MW100  
HFR-SE500

Initialed by: /S/ 5/1/98  
Final: May 7, 1998/dnk

APPROVAL

APPEARS THIS WAY  
ON ORIGINAL

APPEARS THIS WAY  
ON ORIGINAL

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 16832/S016**

**CHEMISTRY REVIEW(S)**

MAY 5 1998

CHEMIST REVIEW  
of SUPPLEMENT

1. ORGANIZATION: HFD-120  
2. NDA NUMBER: 16-832  
3. SUPPLEMENT NUMBERS/DATES: SCP-016 (CBE supplement)  
Letter date: November 25, 1997  
Stamp date: November 26, 1997  
4. AMENDMENTS/REPORTS/DATES:  
a. SCP-016 (BL) Amendment 2/5/98; NAI on 5/4/98

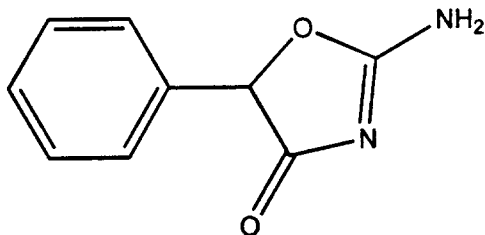
5. RECEIVED BY CHEMIST: 1/29/98

6. APPLICANT NAME AND ADDRESS: Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, Illinois 60064-3500

7. NAME OF DRUG: Cylert®

8. NONPROPRIETARY NAME: pemoline

9. CHEMICAL NAME/STRUCTURE: 4 (5H) -oxazolone, 2-amino-5-phenyl-



10. DOSAGE FORM(S): Tablet

11. POTENCY: 18.75mg, 37.5mg, and 75mg

12. PHARMACOLOGICAL CATEGORY: Attention Deficit hyperactivity disorder

13. HOW DISPENSED:  RX  OTC

14. RECORDS & REPORTS CURRENT:  YES  NO

REVIEW RECORDS & REPORTS CURRENT:  YES  NO

16. SUPPLEMENT PROVIDES FOR: A new closure design.  
Data and information for the following caps and bottles

will be printed with "Sealed for Your Protection". Also, the following statement is added to the label bottles:  
"Do not accept if seal over bottle opening is broken or missing".

The

17. CONCLUSIONS AND RECOMMENDATIONS: APPROVAL

APPEARS THIS WAY  
ON ORIGINAL

18. REVIEWER NAME

SIGNATURE

DATE COMPLETED

Donald N. Klein, Ph.D.

DS

5/5/98

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ON ORIGINAL

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ON ORIGINAL



NDA 16-832, SCP-016

Cylert Tablets, Abbott Labs

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cc:

NDA 16-832

HFD-120/Division File

HFD-810/CHOiberg

HFD-810/JSimmons

HFD-120/MGuzewski

HFD-120/RSeevers

HFD-120/DKlein

HFD-120/AMHomonnay

File: C:\hfd120\N16832\SCP016Review

*/S/ S.S.98*

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