

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 17703/S014

Trade Name: CYLERT CHEWABLE TABLETS

Generic Name: PEMOLINE

Sponsor: ABBOTT LABORATORIES

Approval Date: 5/13/98

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

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APPLICATION: 17703/S014

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

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Application Number: 17703/S014

APPROVAL LETTER

MAY 13 1998

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

APPEARS THIS WAY
ON ORIGINAL

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) Chewable Tablets, 37.5mg.

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

APPEARS THIS WAY
ON ORIGINAL

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

The supplemental application provides for a new closure design.

Cylert®(pemoline) Chewable Tablets. Data and information for the following cap and bottle for Cylert®(pemoline) Chewable Tablets

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

We note that the stability testing should be initiated on the first production batch of Cylert®(pemoline) Chewable Tablets based on the approved protocol. 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 17-703/S-014
HFD-120/Division Files
HFD-AMHomonnay /S/ 5/12/98
HFD-120/DKlein /S/ 5/12/98
/MGuzewska 4⁰ 5.12.98
HFD-810/JSimmons /S/
HFD-92/DDM/DIAB
HFR-SE500

Initialed by: /S/ 5/12/98
Final: May 12, 1998/dnk

APPROVAL

ON ORIGINAL

ON ORIGINAL

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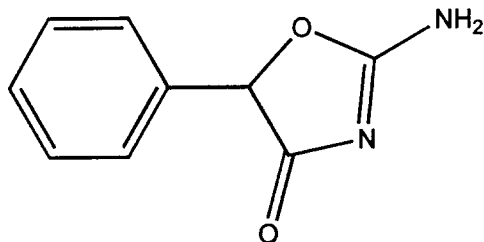
APPLICATION NUMBER: 17703/S014

CHEMISTRY REVIEW(S)

MAY 12 1998

CHEMIST REVIEW
of **SUPPLEMENT**

1. ORGANIZATION: HFD-120
2. NDA NUMBER: **17-703**
3. SUPPLEMENT NUMBERS/DATES: SCP-014 (CBE supplement)
Letter date: November 25, 1997
Stamp date: November 26, 1997
4. AMENDMENTS/REPORTS/DATES:
a. SCP-014 (BL) Amendment 2/5/98; NAI on 5/11/98
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® Chewable
8. NONPROPRIETARY NAME: Pemoline
9. CHEMICAL NAME/STRUCTURE: 4(5H)-oxazolone, 2-amino-5-phenyl-



10. DOSAGE FORM(S): Tablets
11. POTENCY: 37.5mg
12. PHARMACOLOGICAL CATEGORY: Attention deficit hyperactivity disorder
13. HOW DISPENSED: RX OTC
14. RECORDS & REPORTS CURRENT: YES NO
REVIEW RECORDS & REPORTS CURRENT: YES NO

APPEARS THIS WAY
ON ORIGINAL

NDA 17-703, SCP-014

Cylert Tablets(chewable), Abbott Labs

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16. **SUPPLEMENT PROVIDES FOR:** A new closure design
Data and information for the following cap and bottle

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

17. **CONCLUSIONS AND RECOMMENDATIONS: APPROVAL**

18. REVIEWER NAME

SIGNATURE

DATE COMPLETED

Donald N. Klein, Ph.D.

/S/

5/12/98

APPEARS THIS WAY
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NDA 17-703, SCP-014

Cylert Tablets(chewable), Abbott Labs

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cc:

NDA 17-703

HFD-120/Division File

HFD-810/JSimmons

HFD-120/MGuzewska

HFD-120/RSeevers

HFD-120/DKlein

HFD-120/AMHomonnay

File: C:\hfd120\N17703\SCP014Review

/S/ S. 12.98

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