

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40-300

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO.2

2. ANDA 40-300

3. NAME AND ADDRESS OF APPLICANT

Mallinckrodt, Inc.
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134-0840

4. LEGAL BASIS FOR SUBMISSION

The legal basis for this ANDA for Methylphenidate Hydrochloride Tablets (5 mg, 10 mg and 20 mg) is **RITALIN®** (NDA 10-187) owned by CIBA Pharmaceutical Company, a Division of CIBA-GEIGY Corporation. Copies of the relevant pages of the 17th Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations are provided.

5. SUPPLEMENT(s) N/A

6. ESTABLISHED NAME

Methylphenidate Hydrochloride

7. PROPRIETARY NAME

N/A

8. SUPPLEMENT(s) PROVIDE(s) FOR: Original ANDA

9. AMENDMENTS AND OTHER DATES:

Firm

Orig. submission 2/27/98
New correspondence 3/11/98
Amendment 4/8/98
Amendment (Bio info) 6/8/98

Amendment 8/18/98
Amendment 9/9/98
Amendment (phone) 10/23/98
Amendment (phone) 11/24/98

FDA

CSO review 1/11/98
Acknowledgment letter 3/17/98

Bio review 6/30/98
Labeling review 7/20/98
FAX deficiency 7/20/98

This review covers submission dated 8/18, 9/9, 10/23 and 11/24/98

10. PHARMACOLOGICAL CATEGORY

Stimulant (central) - Indicated for Attention Deficit Disorders (previously known as Minimal Brain Dysfunction in Children) and narcolepsy.

11. Rx or OTC
R
12. RELATED DMF(s)
DMF #

X

liner.

13. DOSAGE FORM
Tablet (Oral)
14. POTENCY
5 mg, - 10 mg and 20 mg
15. CHEMICAL NAME AND STRUCTURE
Methyl α -phenyl-2-piperidineacetate hydrochloride.
C₁₄H₁₉NO₂.HCl Molecular weight: 269.77

CAS-298-59-9
16. RECORDS AND REPORTS N/A

17. COMMENTS

- a. Application is SATISFACTORY for approval
- b. Labeling review SATISFACTORY, dated 9/4/98
- c. ~~EPO~~ review SATISFACTORY, dated 6/10/98
- d. Methods validation is not required. Drug substance and drug product are compendial.
- e. DMF is ADEQUATE, dated 9/29/98
- f. Establishment Evaluation Request found ACCEPTABLE, dated 3/24/98.

18. CONCLUSIONS AND RECOMMENDATIONS

APPROVE

19. REVIEWER:

Raymond Brown

DATE COMPLETED:

November 24, 1998

Page(s)

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Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

Chem Rev. 2

11/24/98