APPLICATION NUMBER:
40-300

CHEMISTRY REVIEW(S)
CHEMISTRY REVIEW NO. 2

ANDA 40-300

NAME AND ADDRESS OF APPLICANT
Mallinckrodt, Inc.
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134-0840

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.

SUPPLEMENT(s) N/A

ESTABLISHED NAME
Methylphenidate Hydrochloride

PROPRIETARY NAME N/A

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

AMENDMENTS AND OTHER DATES:

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

PHARMACOLOGICAL CATEGORY
Stimulant (central) - Indicated for Attention Deficit Disorders (previously known as Minimal Brain Dysfunction in Children) and narcolepsy.
11. Rx or OTC
Rx

12. RELATED DMF(s)
DMF #

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. 
C₉H₁₄NO₂·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. Bio 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

18. **CONCLUSIONS AND RECOMMENDATIONS**
    **APPROVE**

19. **REVIEWER:**
    Raymond Brown
    **DATE COMPLETED:**
    November 24, 1998
Contain Trade Secret, Commercial/Confidential Information and are not releasable.

Chem Rev. 2

11/24/98