

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number** 21-121

**MICROBIOLOGY REVIEW(S)**

OCT - 5 1999

REVIEW FOR HFD-120

OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF HFD-805  
Microbiologist's Review of NDA 21-121

*Homonay*

September 21, 1999

- A. 1. NDA NUMBER: NDA 21-121
  
- APPLICANT: Alza Corporation  
950 Page Mill Road  
P.O. Box 10950  
Palo Alto, CA 94303-0802  
650-494-5000
  
- 2. PRODUCT NAME: OROS® (methylphenidate HCl)
  
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Methylphenidate HCl  
18 mg and 36 mg tablets, oral dosage.
  
- 4. METHOD OF STERILIZATION: none (non-sterile product)
  
- 5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION: Central nervous system stimulant. Proposed indication: Attention Deficit/Hyperactivity Disorder (ADHD) in children.
  
- B. 1. DATE OF INITIAL SUBMISSION: July 15, 1999
  
- 2. CONSULT DATE: August 16, 1999
  
- 3. ASSIGNED FOR REVIEW: August 27, 1999
  
- 4. RELATED DOCUMENTS: 8/28/98 submission (IND 54,575)

C. REMARKS:

NDA 21-121, Vol. 1.4 p. 102-104 (Microbiology Summary), Vol. 1.5 p. 296-314 (Specifications), and Vol. 1.7 p. 95-127 (Stability) were provided for consult review.

The 8/28/98 submission \_\_\_\_\_ provided for elimination of microbial limits specification of the drug products.

**D. CONCLUSIONS:** The application is recommended for approval for issues concerning product quality microbiology. Specific comments are provided in section "E. Review Notes".

ISI 9/21/99  
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Neal Sweeney, Ph.D.

cc: NDA 21-121  
HFD-120 Division File  
HFD-120/D. Klein A.M. Homonnay  
HFD-805/Consult file/N. Sweeney

Drafted by: N. Sweeney, September 21, 1999  
R/D Initialed by: P. Cooney, September 21, 1999

ISI HC  
10-5-99

