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RESEARCH**

APPLICATION NUMBER:

21-338

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-170

April 21, 2004

NDA: 21-338

Drug Product Name

Proprietary: — (TM) (proposed)

Non-proprietary: (fentanyl HCL) System
(Generic Descriptor TBD)

Drug Product Classification:

Review Number: 1

Subject of this Review

Submission Date: September 23, 2003

Receipt Date: September 24, 2003

Consult Date: January 23, 2004

Date Assigned for Review: March 15, 2004

Submission History (for amendments only)

Date(s) of Previous Submission(s): Not applicable

Date(s) of Previous Micro Review(s): Not applicable

Applicant/Sponsor

Name: ALZA Corporation

Address: 1900 Charleston Road P.O.
Box 7210
Mountain View, CA
94039-7210

Representative: Susan P. Rinne

Telephone: 650-564-2523

Name of Reviewer: John W. Metcalfe, Ph.D

Conclusion: Recommended for approval
based on microbiological
product quality

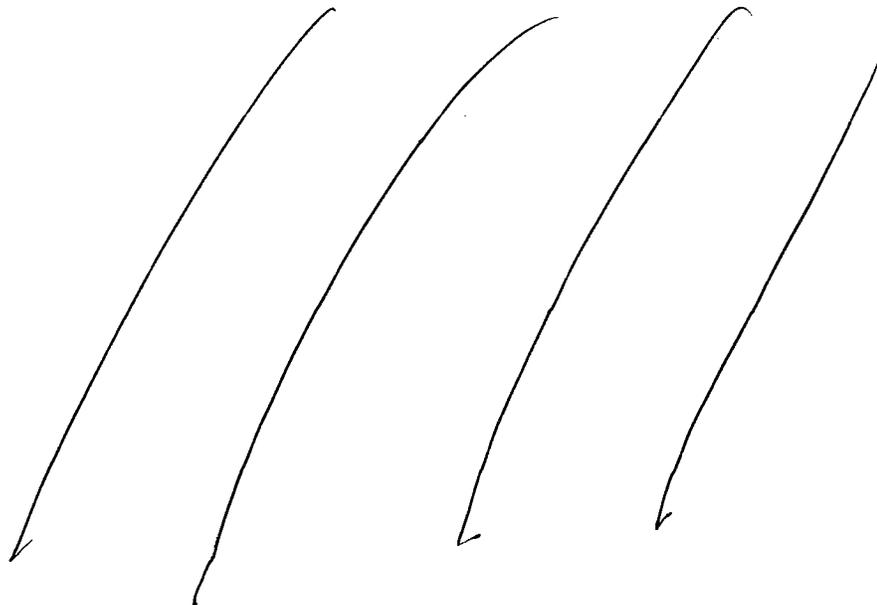
Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – Approve
- B. **Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – Not applicable

II. Summary of Microbiology Assessments

- A. **Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** –



- B. **Brief Description of Microbiology Deficiencies** – There are no microbiology deficiencies.
- C. **Assessment of Risk Due to Microbiology Deficiencies** – Not applicable.

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
John W. Metcalfe, Ph.D.
Peter Cooney, Ph.D.
- C. **CC Block**
In DFS

6 Page(s) Withheld

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§ 552(b)(5) Deliberative Process

§ 552(b)(4) Draft Labeling

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/s/

John Metcalfe
4/27/04 02:10:04 PM
MICROBIOLOGIST

Peter Cooney
4/27/04 02:35:50 PM
MICROBIOLOGIST