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RESEARCH**

APPLICATION NUMBER:

21-569

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD-170

11 May 2003

NDA: 21-569

Drug Product Name Sodium Chloride Injection USP 0.9%

Proprietary: Not Applicable
Non-proprietary: Sodium Chloride Injection USP, 0.9%
Drug Product Classification:

Review Number: 1

Subject of this Review

Submission Date: September 30, 2002
Receipt Date: October 1, 2002
Consult Date: November 15, 2002
Date Assigned for Review: November 19, 2002

Submission History (for amendments only)

Date(s) of Previous Submission(s):
Date(s) of Previous Micro Review(s):

Applicant/Sponsor

Name: Mallinckrodt Inc./TYCO Healthcare
Address: 675 McDonnell BLVE
St. Louis, MO 63134

Representative: Edward R. Porter
Telephone: 314-654-6061

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Executive Summary**I. Recommendations****A. Recommendation on Approvability -**

NDA 21-569 is recommended for approval from the standpoint of microbial product quality

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**II. Summary of Microbiology Assessments****A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -**

50 and 125 ml _____ syringes are filled with sodium chloride _____

B. Brief Description of Microbiology Deficiencies -

No deficiencies were identified based upon the information provided.

C. Assessment of Risk Due to Microbiology Deficiencies -
Not applicable**III. Administrative****A. Reviewer's Signature _____****B. Endorsement Block**

Stephen E. Langille, Ph.D.
Peter Cooney, Ph.D.

C. CC Block
In DFS

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/s/

Stephen Langille
7/14/03 09:05:05 AM
MICROBIOLOGIST

Peter Cooney
7/14/03 01:46:06 PM
MICROBIOLOGIST