

M I C R O

OCT 26 1999

**REVIEW TO HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY TEAM
MICROBIOLOGY REVIEW OF NDA
14 OCTOBER, 1999**

- A. 1. **NDA 21-117**
PRODUCT NAME: 10% Calcium Chloride Injection, USP
- APPLICANT: Abbott Labs**
200 Abbott Park Road
Abbott Park, IL 60064-6157
- B. 1. **DOSAGE FORM: 10 mL Plastic Syringe, 10% strength for I.V. use**
2. **METHODS OF STERILIZATION:** [REDACTED]
3. **PHARMACOLOGICAL CATEGORY/PRINCIPAL INDICATION:**
Treatment of hypocalcemia [REDACTED]
- C. 1. **DATE OF SUBMISSION: April 9, 1999**
2. **General Correspondence: April 9, 1999**
3. **DRUG PRIORITY: S**
- D. **REMARKS:** The NDA contains validation information for the terminal sterilization of the drug product. The general correspondence also dated April 9, 1999 contains some minor changes made to the contents of the NDA. Abbott currently markets Calcium Chloride Injection in an Abboject glass container. This submission provides for the use of a polypropylene plastic syringe. Other products approved for use in plastic syringes are listed in the submission as supporting references:

NDA/ANDA Number	Product	Approval Date
NDA 19-445/S-002	50% Dextrose Injection	1/27/98
ANDA 75-005	Iopamidol Injection	2/24/98
NDA19-030/S-008	Bretylum Tosylate Injection	3/13/98
NDA 18-801/S-014	Sterile Water for Injection	8/14/98
ANDA 40-302	1 % & 2% Lidocaine HCl Injection	9/17/98
ANDA 75-136	Verapamil Injection	10/20/98
NDA 19-217/S-004	0.9% Sodium Chloride	11/18/98
NDA 19-445/S-004, S-006	25 % Dextrose Injection	11/23/98
NDA 19-217/S-006	0.9 % Sodium Chloride Injection	4/1/99

E. **CONCLUSIONS:** The NDA 21-117 is recommended for approval from the standpoint of product quality microbiology. Please see section F for Review Notes.

IS/ 14 Oct 1999

APPEARS THIS WAY
ON ORIGINAL

Patricia F. Hughes, Ph.D.
Microbiology Reviewer

IS/ 10/26/99

cc.: Original NDA 21-117
HFD-510/Div.Files
HFD-510/SmcCort/DLewis
HFD-160/Consult Files
HFD-805/PFHughes
Drafted by PFHughes, 14 October 1999
R/D Initialed by PHCooney

APPEARS THIS WAY
ON ORIGINAL