

BPH

CLINICAL PHARMACOLOGY & BIOPHARMACEUTICS REVIEW

NDA 21-117 / N-000

SUBMISSION DATE: 29-MAR-99, 09-APR-99(BZ),
30-JUL-99(BZ)

GENERIC NAME: 10% calcium chloride injection

REVIEWER: Robert M. Shore, Pharm.D.

SPONSOR: Abbott Laboratories,
Abbott Park, IL

TYPE OF SUBMISSION: Original Application

BACKGROUND:

10% calcium chloride injection (100mg/mL) is currently available in a 10mL glass syringe. This product contains a solution not previously approved under an NDA and was marketed before 1938. The sponsor proposes to repackage this product in a plastic single-use syringe and, as per Agency recommendations (letters dated 03-SEP-96 from Dr. Roger Williams and 06-NOV-98 from Dr. Murray Lumpkin), has filed this change under section 505(b)(2) of the FD&C Act. This product, as per MaPP 6020.2 issued 06-SEP-96, is considered a small volume parenteral.

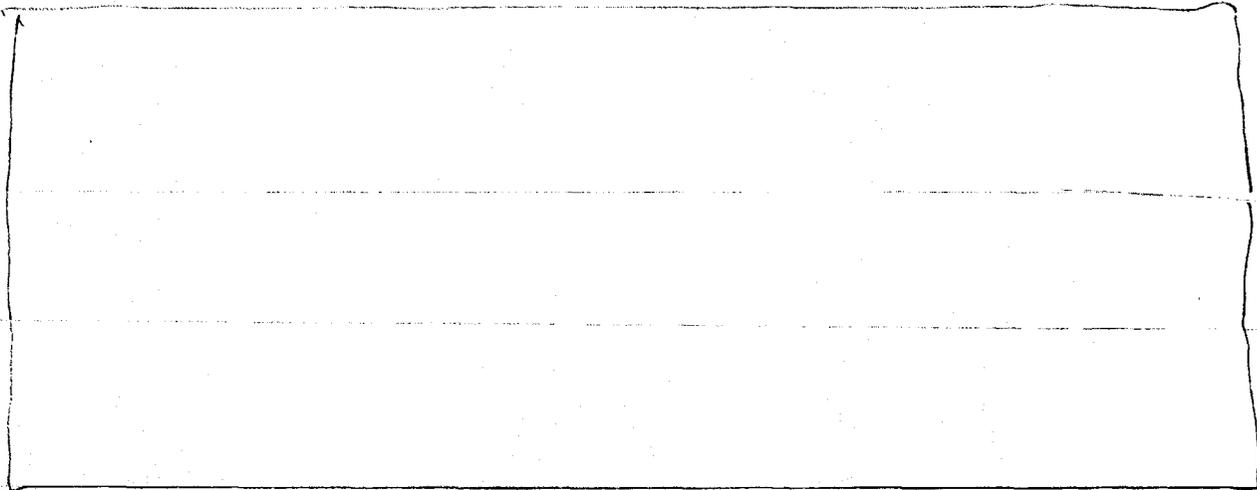
SUBMISSION:

According to the proposed labeling, 10% calcium chloride is indicated (1) for the treatment of hypocalcemia in those conditions requiring a prompt increase in blood plasma calcium levels.

DISCUSSION:

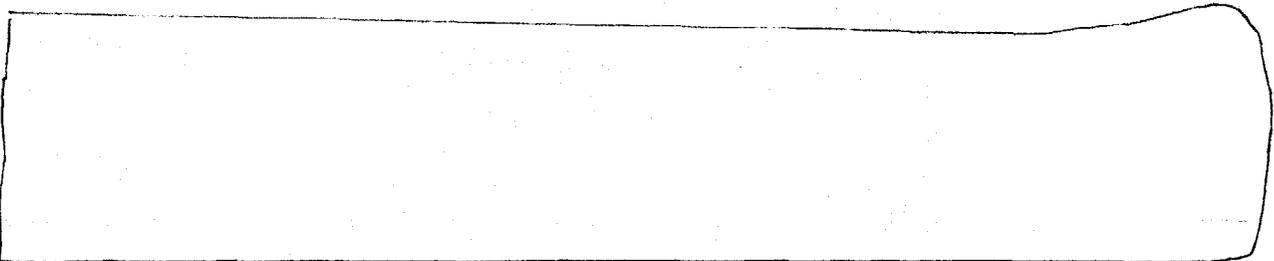
Although there are a number of IV parenteral products with calcium chloride currently approved, none has the same concentration of active ingredient as this 10% product. Therefore, waiver of evidence of *in vivo* bioavailability, as per 21CFR 320.22(b)(1) cannot be granted.

There is published literature (included in this submission) about IV calcium chloride and its usefulness in raising calcium concentrations in serum. Since there are a number of products already approved which contain calcium chloride, and the calcium component is dissociated and fully bioavailable, the requirement for evidence of *in vivo* bioavailability can be waived under 21CFR 320.22(e) for good cause.

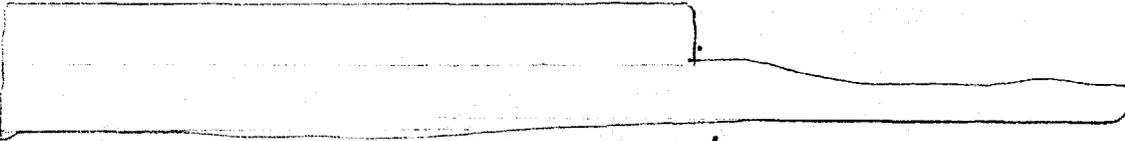


COMMENTS TO BE SENT TO MEDICAL OFFICER:

1) The labeling under **DESCRIPTION** reads as follows:



2) The labeling under **INDICATIONS AND USAGE** reads as follows:



Robert M. Shore, Pharm.D.
Division of Pharmaceutical Evaluation II
Office of Clinical Pharmacology and Biopharmaceutics

/S/ 26-OCT-99

RD initialed by Hae-Young Ahn, Ph.D., Team Leader 26-OCT-99

FT initialed by Hae-Young Ahn, Ph.D., Team Leader */S/* 10/23/99

CC: NDA 21-117/N-000 (orig.,1 copy), HFD-510(McCort, Zawadzki, Lewis, Steigerwalt), HFD-870(Ahn, ChenME), CDR (Barbara Murphy).

Code: AP

APPEARS THIS WAY
ON ORIGINAL

Proposed Labeling

2 pages
REDACTED
DRAFT
LABELING