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Application Number 21-160

PHARMACOLOGY REVIEW(S)

NDA 21-160

Review Completed: February 8, 2000

Sponsor: Braintree Laboratories, Inc.; Braintree, MA 02185-0929

PHARMACOLOGY REVIEW OF NDA SUPPLEMENT
NDA 21-160

DRUG: PhosLo Caps

CATEGORY: calcium acetate

INDICATION: Control of hyperphosphatemia in end stage renal failure.

This submission provides for the addition of a new dosage form, 2 capsule strengths and 1 gelcap strength. There were no changes made to the preclinical sections of the label. There is no need for further action from pharmacology.

RS
Ronald W. Steigerwalt, Ph.D.
Pharmacology Team Leader

2/8/00

cc: NDA Arch
HFD510
HFD510/Steigerwalt/Hedin
Recommendation code: AP
Filename:21160.000.doc

PROCESS
ORIGINAL REVIEW