

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number** 21-160

**MEDICAL REVIEW(S)**

**MEDICAL OFFICER REVIEW OF NEW DRUG APPLICATION**

**NDA No, 21-160**

**DRUG: PhosLo®**

Calcium acetate

**SPONSOR:** Braintree Laboratories  
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PO Box 850929  
Braintree, MA 02185-0929  
Tel: 781-843-2202

**DATE SUBMITTED:** June 3, 1999

**DATE REC'D, CDER:**

**DATE REC'D, M.O.:** Feb. 23, 2000

**DATE REVIEWED:** Feb. 29, 2000

**INDICATION:** Control of hyperphosphatemia in end stage renal disease

This supplemental application is for an additional dosage form – capsule – to be manufactured in two dosages, 667 mg and 333.5 mg.

No clinical information is submitted. The specific changes are of the drug product: composition, inactive ingredients, methods of manufacturing and packaging, specifications, and stability. These changes will be reviewed by the Chemistry Reviewer.

Draft labeling is submitted describing the new forms. The remainder of the label is identical to that for the presently approved tablet containing 667 mg of calcium acetate. I have two questions concerning the label:

1. The tablet form of the product is mentioned in the sections entitled **HOW SUPPLIED** and at the end of the label. This dosage form is not mentioned under **DOSAGE AND ADMINISTRATION** or under **DESCRIPTION**. Will the tablet form remain available? If so, should there be cross-referencing between the labels?
2. I find no data demonstrating equivalence of the tablet and capsule forms of the product. The label implies this equivalence and should be supported by information.

Since no clinical studies are reported, there is no basis for a medical opinion concerning approvability.

  
Leo Lutwak, M.D., Ph.D., F.A.C.P.  
Medical Officer  
February 29, 2000

  
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HFD-510/HedinR/ColmanE/LutwakL/SchnedierB/ZilbersteinM

**APPEARS THIS WAY  
ON ORIGINAL**