



BANNER
PHARMACAPS



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October 8, 2003

Dr. Christine L. Taylor, Ph.D
Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-810)
CFSAN - FDA
5100 Paint Branch Pkwy
College Park, MD 20740

Dear Dr. Taylor:

Pursuant to the provisions set forth in 21 CFR 101.93, Banner Pharmacaps Inc. of 4125 Premier Drive, High Point NC 27265 (the manufacturer of Calcium Carbonate plus Stool Softener) is providing notification of the marketing and labeling of such dietary supplement.

The text to be included on the labeling is as follows:

- Calcium Carbonate: may reduce the risk of osteoporosis
- Calcium Carbonate plus a Stool Softener: may reduce the constipation commonly associated with calcium alone.
- being widely recognized within the medical community that calcium hardens stools, with the addition of docusate sodium, a well established, gentle stool softener and food additive, not only is the risk of osteoporosis decreased, but now it is possible to treat your bones well without the constipation side effects
- the combination of Calcium Carbonate and Docusate Sodium is gentler on the digestive tract
- Calcium Carbonate is doctor recommended and nature's most concentrated form of calcium
- It is the only non-constipating calcium formula
- These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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Currently the marketing of this product will be under the name "Calcium Carbonate plus Stool Softener". There has been no trade name determined at this time.

Should you have any questions regarding this notification, please contact me at 336-812-8676 ext. 3312.

Sincerely,



Donna Lee Finch, R.Ph.
Director of Regulatory Affairs &
Project Management