DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-862/S-018

Bone Care International
Attention: Ms. Jill Dunaway
Manager, Regulatory Affairs
1600 Aspen Commons
Middleton, WI 53562

Dear Ms. Dunaway:

Please refer to your supplemental new drug application dated April 29, 2005, received May 2, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hectorol (doxercalciferol) Capsules, 0.5 mcg and 2.5 mcg.

This "Changes Being Effected" supplemental new drug application provides for changes to the **Drug Interaction** subsection of the **PRECAUTIONS** section of the Hectorol Capsule package insert.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the attached final printed labeling (FPL) submitted on April 29, 2005.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Pat Madara, Regulatory Project Manager, at (301) 827-6416.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: package insert

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Parks
6/24/05 09:40:49 AM
for Dr. Orloff