DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-862/S-016

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

Dear Ms. Dunaway:

Please refer to your supplemental new drug application dated September 10, 2004, received September 13, 2004, 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 minor labeling changes to the immediate containers and cartons for 0.5 mcg and 2.5 mcg strengths of Hectorol Capsules.

We completed our review of this supplemental new drug application and it is approved, effective on the date of this letter.

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

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

/s/

David Orloff

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