DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-027/S-007

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

Dear Ms. Dunaway;

Please refer to your supplemental new drug application dated February 6, 2003, received February 7, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hectorol® (doxercalciferol) Injection, 2 µg/mL.

We acknowledge receipt of your submission dated August 14, 2003, which constitutes a complete response to our August 6, 2003 action letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of an alternate manufacturing site(b)(4)---------- for the 2 mL ampule size of Hectorol Injection.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the following minor editorial revision: The **Information for the Patient** subsection of the **PRECAUTIONS** section of the package insert should be changed from "…The patient, spouse, or guardian should be informed about compliance with adherence to instructions about diet, calcium..." to "…The patient, spouse, or gurardian should be informed about adherence to instructions about diet, calcium…"

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the submitted labeling (package insert, submitted August 14, 2003, immediate container and carton labels submitted February 6, 2003). This revision is a term of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-027/S007." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (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
(HFD-510)
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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