DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-229/S-030

Ortho Biotech products, LLC.
920 US Highway 202 South
P.O. box 300
Raritam, NJ 08869-0602

Attention: Brian Maloney, RPh, MS
Associate Director, Global Regulatory Affairs

Dear Mr. Maloney:

Please refer to your supplemental new drug application dated April 13, 2006, received April 14, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Leustatin® (cladrabine) for Injection.

This supplemental new drug application provides for a revision to the package insert, Adverse Reactions section to include "Rare cases of Myelodysplastic syndrome have been reported" under Hematologic adverse events.

We completed our review of this supplemental application. This supplemental application is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 13, 2006.

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 Ann Staten, Regulatory Project Manager, at (301) 796-1468

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Director
Division of Drug Oncology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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

/s/

Ann Farrell
6/29/2006 02:52:12 PM
Farrell for Justice