DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-229/S-021

Ortho Biotech Products, L.P.
C/o Johnson & Johnson Pharm. Research & Development, L.L.C.
920 Route 202 South
P.O. Box 300
Raritan, New Jersey 08869-0602

Attention: Patricia Capaccione, Senior Regulatory Associate
Global Marketed Products

Dear Ms. Capaccione:

Please refer to your supplemental new drug application dated August 25, 1999, received August 26, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Leustatin® (cladribine).

We acknowledge receipt of your submission dated May 8, 2002. We also refer to the labeling revisions detailed in the August 20, 2002 approval letter for supplement 007.

This supplemental new drug application provides for draft labeling for the Geriatric Use subsection.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted August 25, 1999 and revision submitted May 8, 2002) and should contain the changes listed in the August 20, 2002 approval letter for supplement 007. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-229/S-021." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Ann Staten, Project Manager, at (301) 594-0490.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
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/

Richard Pazdur

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