DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-257/Original – 1
NDA 21-304 S-07

NDA APPROVAL

Roche Palo Alto LLC
c/o Hoffmann-La Roche, Inc.
Attn: Wendy L. Corbett, Ph.D., MBA
Associate Director, Pharma Development Regulatory
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Dr. Corbett:

Please refer to your new drug application (NDA) dated April 30, 2008, received May 1, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valcyte® (valganciclovir hydrochloride) for oral solution. For administrative purposes, we have separated your pediatric kidney and heart transplant indication into NDA 22-257/Original – 1.

We acknowledge receipt of your submissions dated:

May 21, 2008	May 28, 2008	June 13, 2008
June 17, 2008	July 11, 2008	July 18, 2008
July 29, 2008	August 15, 2008	September 26, 2008
October 10, 2008	October 20, 2008	October 22, 2008
October 24, 2008	October 29, 2008	November 4, 2008
November 25, 2008	December 15, 2008	December 23, 2008
February 2, 2009	February 11, 2009	March 23, 2009
June 26, 2009	August 6, 2009	August 18, 2009

The June 26, 2009 submission constituted a complete response to our November 25, 2008 action letter. We also acknowledge receipt of your August 6, 2009 supplemental new drug application (sNDA) NDA 21-304 S-07, submitted under section 505(b) of the Federal Food, Drug, and Comestic Act for Valcyte® (valganciclovir hydrochloride) tablets.

These new drug applications provide for the use of Valcyte® (valganciclovir hydrochloride) for oral solution and Valcyte® (valganciclovir hydrochloride) tablets for the prevention of cytomegalovirus (CMV) disease in pediatric kidney and heart transplant patients ≥ 4 months of age at high risk of developing CMV.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm that is identical to the enclosed labeling (text for the package insert and text for the patient package insert). For administrative purposes, please designate this submission, "**SPL for approved NDA 22-257/Original - 1 and SPL for approved sNDA 21-304/S-07**."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-257/Original - 1**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for ages 4 months to 16 years of age for pediatric solid organ transplant patients. You also fulfilled the pediatric study requirements for pediatric congenital CMV disease.

POSTMARKETING COMMITMENTS

We remind you of your postmarketing study commitments in your submission dated August 28, 2009. These commitments are listed below.

1533-1 Analyze the phenotypic nature of ganciclovir resistant viruses isolated during the clinical study CASG 109. Submit the results in a SAS transport file dataset.

Protocol Submission:	COMPLETED
Study Start:	COMPLETED
Final Virology Report Submission:	June 30, 2010

1533-2 Perform a pharmacokinetic and safety study in pediatric heart transplant recipients <4 months of age in order to determine appropriate dosing in this age group and submit dosing recommendations for inclusion in the package insert.

Protocol Submission:	June 30, 2010
Study Start:	October 1, 2010
Final Report Submission:	March 31, 2013

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments should be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Jaewon Hong, Pharm.D., Regulatory Project Manager, at (301) 796-2013.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure
(draft package insert, draft patient package insert, draft carton and container labels)

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

/s/

JAEWON HONG
08/28/2009

DEBRA B BIRNKRANT
08/28/2009