DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 205220

ANDA APPROVAL

Actavis Laboratories FL, Inc.
2945 West Corporate Lakes Blvd, Suite B
Weston, FL 33331
Attention: Janet Vaughn

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Valganciclovir Hydrochloride for Oral Solution, 50 mg/mL.

Reference is also made to your amendments dated June 28, 2013; February 18, 2014; January 23, April 21, August 6, August 7, August 14 and September 1, 2015; January 11, January 14, March 1, March 10, March 14 and March 24, 2016.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. **Accordingly the ANDA is approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Valganciclovir Hydrochloride for Oral Solution, 50 mg/mL to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Valcyte (Valganciclovir Hydrochloride) Powder for Oral Solution, 50 mg/mL of Hoffman-La Roche Ltd.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), 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 in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Carol Holquist

Digitally signed by Carol Holquist
Date: 7/18/2016 07:28:34PM
GUID: 508da712000293e0f6d8acfd3c5e67fe

Amir, Nazmin

From: Kreger, Jessica <Jessica.Kreger@fda.hhs.gov>
Sent: Tuesday, July 19, 2016 9:11 AM
To: Regulatory Affairs US
Cc: Carr, Lakeeta
Subject: ANDA 205220, Valganciclovir Hydrochloride for Oral Solution, 50 mg/mL - Full Approval
Attachments: A205220N000AP.pdf

Good afternoon,

On behalf of Lakeeta Carr, ANDA **205220** for **Valganciclovir Hydrochloride for Oral Solution, 50 mg/mL** has been fully approved. A courtesy copy of the signed approval letter is attached. You will also receive a hard copy in the mail.

Please confirm receipt of this email.

Congratulations to you and your team.

Sincerely,

Jessica Kreger, PharmD, PMP
LCDR, U.S. Public Health Service
Regulatory Project Manager
Special Assistant to Rear Admiral Schweitzer, CPO Pharmacy
Division of Project Management
Office of Regulatory Operations
Office of Generic Drugs
Food & Drug Administration
(240) 402-3957