



NDA 19-910/S-035

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Martha Anne A. Moore, R.Ph.
Senior Director, Infectious Diseases, US Regulatory Affairs
P.O. Box 13398
Five Moore Drive,
Research Triangle Park, NC 27709

Dear Ms. Moore:

Please refer to your supplemental new drug applications dated and received May 7, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RETROVIR® (zidovudine) syrup.

We acknowledge receipt of your submissions dated June 5, 2009, June 19, 2009, and October 26, 2009.

This prior approval supplemental new drug application provides dosing recommendations for patients aged 4 weeks to less than 6 weeks and weighing at least 4 kg for the treatment of HIV-1 infection in combination with other antiretroviral agents. In addition, the "Patient Counseling" section was updated to include information related to HIV-1/HCV co-infection, lactic acidosis/hepatomegaly, and myopathy.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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)(1)(i)] 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 patient package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 19-910/S-035.

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format that includes the changes approved in this supplemental application.

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 all relevant pediatric age groups for this application.

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
5600 Fishers Lane, Room 12B05
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 Robert G. Kosko, Jr., Pharm.D., M.P.H., Regulatory Project Manager, at (301) 796-3979.

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
Package Insert

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-19910

SUPPL-35

GLAXOSMITHKLIN
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RETROVIR SYRUP

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

/s/

JEFFREY S MURRAY

11/06/2009