



NDA 22-011/S-003
NDA 22-154/S-001

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Michael S. Buska
Director, Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Buska:

Please refer to your supplemental new drug application dated June 5, 2009, received June 5, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tyzeka® (telbivudine) 600 mg tablets and Tyzeka (telbivudine) oral solution 100 mg/5 mL.

We acknowledge receipt of your submissions dated October 22, 2009, December 7, 2009 and February 1, 2010.

These prior approval supplemental new drug applications provide revisions to the Nonclinical Toxicology-Carcinogenesis, Mutagenesis, Impairment of Fertility section (13.1) of the Tyzeka® (telbivudine) US package insert with results of data obtained from a recently completed juvenile rat toxicology study. In addition, based on our review of postmarketing adverse events from the AERS database and your Periodic Safety Update Reports, the Division made revisions to the Warnings and Precautions (5.3) section of the package insert.

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/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert). For administrative purposes, please designate this submission, "**SPL for approved NDA 22-011/S-003 and NDA 22-154/S-001.**"

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 Stacey Min, Pharm.D., Regulatory Project Manager, at (301) 796-4253.

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

Food and Drug Administration

Enclosure

Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22154	SUPPL-1	NOVARTIS PHARMACEUTICA LS CORP	TYZEKA (TELBIVUDINE) ORAL
NDA-22011	SUPPL-3	NOVARTIS PHARMACEUTICA LS CORP	TYZEKA

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/s/

KENDALL A MARCUS
03/04/2010