



NDA 202895
NDA 21976/S-020

NDA APPROVAL
NDA SUPPLEMENT APPROVAL

Tibotec, Inc
Attention: Charles Zezza, Ph.D., M.B.A.
Director, Global Regulatory Affairs
920 Route US Highway 202S
PO Box 300
Raritan, NJ 08869

Dear Dr. Zezza:

Please refer to your New Drug Application (NDA) dated March 29, 2011 received March 30, 2011 and your supplemental NDA dated and received June 28, 2011 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prezista® (darunavir) suspension, 100 mg/mL and tablets, 75 mg, 150 mg, 400 mg, and 600 mg.

We acknowledge receipt of your amendments dated:

| | | |
|----------------|-------------------|--------------------|
| March 29, 2011 | June 30, 2011 | September 9, 2011 |
| April 13, 2011 | July 7, 2011 | September 12, 2011 |
| April 19, 2011 | July 13, 2011 | September 14, 2011 |
| April 26, 2011 | July 19, 2011 | September 21, 2011 |
| April 28, 2011 | July 28, 2011 | September 22, 2011 |
| May 3, 2011 | July 29, 2011 | September 23, 2011 |
| May 9, 2011 | August 4, 2011 | September 28, 2011 |
| June 2, 2011 | August 10, 2011 | November 9, 2011 |
| June 7, 2011 | August 12, 2011 | November 30, 2011 |
| June 9, 2011 | August 18, 2011 | December 12, 2011 |
| June 10, 2011 | August 19, 2011 | December 15, 2011 |
| June 15, 2011 | August 22, 2011 | December 16, 2011 |
| June 23, 2011 | September 1, 2011 | |
| June 28, 2011 | September 8, 2011 | |

The NDA provides for the use of Prezista® (darunavir) oral suspension in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 3 years of age and older and weighing at least 10 kg.

The supplemental NDA updates the Prezista[®] (darunavir) oral tablets labeling within information related to the oral suspension formulation.

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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling text for the package insert and patient package insert. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

For NDA 202895, 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 (June 2008).” 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 202895.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

MARKET PACKAGE

Please submit one market package of the drug product when it is available.

If sending via USPS, please send to:

Linda C. Onaga, MPH
Food and Drug Administration
Center for Drug Evaluation and
Research
White Oak Building 22, Room: 6321
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

If sending via any carrier other than USPS
(e.g., UPS, DHL), please send to:

Linda C. Onaga, MPH
Food and Drug Administration
Center for Drug Evaluation and
Research
White Oak Building 22, Room: 6321
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

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 are waiving the pediatric study requirement for ages 0 to 3 years because there is evidence strongly suggesting that the drug product would be unsafe in this pediatric group. This decision is based on the results of juvenile rat toxicology studies that provide evidence of a potential safety risk as a result of drug-brain accumulation.

This product is appropriately labeled for use in ages 6 to 17 years for this indication. Therefore, no additional studies are needed in this pediatric group.

We note that you have fulfilled the pediatric study requirement for ages 3 to 6 years for this application.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment for NDA 202895:

- 1816-1 Collect dissolution profile data from all full-scale batches manufactured during the first year after approval date. The collection of the dissolution data will target the dissolution specifications recommended by the FDA and will include dissolution testing at Stage 1, 2, or 3 as appropriate. Submit the final dissolution report with complete dissolution information/data, a proposal for final dissolution specifications, and data analysis with the number/percentage of batches tested at Stage 1, 2, or 3 or which failed the dissolution specifications recommended by FDA.

The timetable you submitted on September 9, 2011 states that you will conduct this study according to the following schedule:

| | |
|--------------------------|---------|
| Study Completion: | 12/2012 |
| Final Report Submission: | 03/2013 |

Submit 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/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled “**Postmarketing Commitment Protocol,**” “**Postmarketing Commitment Final Report,**” or “**Postmarketing 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 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, 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>.

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 Linda C. Onaga, MPH, Regulatory Project Manager, at (301) 796-0759.

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(S):

Content of Labeling
Carton and Container Label

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



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FINANCIAL INSTITUTIONS

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E-DISCOVERY AND LEGAL VENDORS

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