



BLA 125036/142

**SUPPLEMENT BLA APPROVAL**

December 28, 2011

Astellas Pharma US, Inc.  
Attention: Scott Nelson  
Senior Manager, Regulatory Affairs  
Three Parkway North  
Deerfield, IL 60015

Dear Mr. Nelson:

Please refer to your Supplemental Biologics License Application (sBLA), dated June 30, 2011, received June 30, 2011, submitted under section 351 of the Public Health Service Act for Amevive<sup>®</sup> (alefacept).

We acknowledge receipt of your amendment dated December 7, 2011.

This "Prior Approval" labeling supplement to your biologics license application provides for the revision of the full prescribing information to meet the new labeling content and format requirements for human prescription drug and biological products according to 21 CFR 201.56(d) and 201.57.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below.

1. Under Highlights, in the Indications and Usage section, cross-reference "(1)" has been added at the end of the sentence.
2. Under Highlights, in the Contraindications section, a bullet has been placed prior to "HIV infection".
3. Under section 6.3 of the Full Prescribing Information, in the Serious Infections subsection, the first cross reference has been revised to "Warnings and Precautions (5.3)...".

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to, including the revisions listed, the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements. 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>. For administrative purposes, please designate this submission “**Product Correspondence – Final SPL for approved BLA STN 125036/142.**”

Also within 14 days, amend all pending supplemental applications for this BLA, including pending “Changes Being Effectuated” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

The SPL will be accessible via publicly available labeling repositories.

### **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.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Paul Phillips, Regulatory Project Manager, at (301) 796-3935.

Sincerely,

/ Tatiana Oussova /  
Tatiana Oussova, M.D., M.P.H.  
Deputy Director for Safety  
Division of Dermatology and Dental Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Content of Labeling