



BLA 125036/144

SUPPLEMENT APPROVAL

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 November 1, 2011, received November 2, 2011, submitted under section 351 of the Public Health Service Act for Amevive[®] (alefacept).

We acknowledge receipt of your amendments dated February 20 and April 17, 2012.

This "Prior Approval" labeling supplement to your biologics license application proposes revisions to the package insert to add postmarketing reports of malignancies and infections, as well as the addition of a Medication Guide.

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 which also includes the minor editorial revisions listed below.

- In Highlights, the reference to section 17 was modified to add "Medication Guide" as follows:

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

- In section 17 of the FPI, a reference to the approved patient labeling was added directly under the section title as follows:

17 PATIENT COUNSELING INFORMATION

"See FDA-approved patient labeling (Medication Guide)"

- In the Medication Guide, under the section "What are the possible side effects of Amevive?", in the subsection "Common side effects of AMEVIVE include:", the instruction in the last bullet, "Tell your doctor if you have any side effect that bothers you or that does not go away", was separated from the bulleted list by a hard return and removing the bullet so the instruction now reads as a stand alone sentence.

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 the enclosed labeling (text for the package insert, Medication Guide) 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 125036/144.**”

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.

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
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 601.12(f)(4), 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 Office of Prescription Drug Promotion (OPDP), 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 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,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

TATIANA OUSSOVA
05/01/2012