



BLA 103000/5253

SUPPLEMENT APPROVAL

Allergan, Inc.
Attention: Melina Dass, MS, RAC
Senior Manager, Global Regulatory Affairs
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92612-9534

Dear Ms. Dass:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received May 10, 2012, submitted under section 351(a) of the Public Health Service Act for BOTOX[®] (onabotulinumtoxinA) Cosmetic for injection.

We acknowledge receipt of your amendments dated July 3, October 17, and November 9, 2012 (2).

This “Prior Approval” supplemental biologics application provides for revisions to the BOTOX[®] Cosmetic Full Prescribing Information to align with the Physician Labeling Rule.

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 and indicated in the enclosed labeling.

1. In the Highlights, Dosage and Administration section, un-bold the first bulleted statement, “Administration: 0.1 mL (4 Units) by intramuscular injection into each of 5 sites, for a total of 20 Units (2.1)”.
2. In the Highlights section, “Initial U.S. Approval: 1989” should appear on its own line.
3. In the Table of Contents, the title for subsection 5.8 should read “Pre-existing Conditions at the Injection Site”.

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, and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effected” (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>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this BLA, including pending “Changes Being Effected” (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.

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 Strother D. Dixon, Regulatory Project Manager, at (301) 796-1015.

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
11/09/2012