



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125274/S-052

**SUPPLEMENT BLA APPROVAL
REMS ASSESSMENT ACKNOWLEDGMENT
RELEASE REMS REQUIREMENT**

Ipsen Biopharmaceuticals, Inc.
Attention: Kevin Schutz, PharmD
Associate Director, Commercial Regulatory Affairs
106 Allen Road
Basking Ridge, NJ 07920

Dear Dr. Schutz:

Please refer to your Supplemental Biologics License Application (sBLA), dated July 13, 2011, received July 15, 2011, submitted under section 351 of the Public Health Service Act for Dysport (abobotulinumtoxinA).

We acknowledge receipt of your amendments dated August 3 and 19, 2011, November 22, 2011, January 31, 2012, and your email correspondence dated March 15, 2012. We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated January 7, 2011. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be complete.

This Prior Approval supplement to your biologics license application provides for labeling changes to your Medication Guide. It also proposes to eliminate the requirement for the Medication Guide as an element of the REMS.

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.

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, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from 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).

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Dysport (abobotulinumtoxinA) was originally approved on April 29, 2009. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS.

Your proposed modification to the REMS consists of eliminating the requirement for the Medication Guide as an element of the REMS.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1, and therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Dysport (abobotulinumtoxinA) outweigh the risks.

Because the assessment demonstrates that the communication plan has been completed and has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, a REMS is no longer required for Dysport (abobotulinumtoxinA).

We remind you that the Medication Guide will continue to be part of the approved labeling for Dysport (abobotulinumtoxinA) in accordance with 21 CFR 208.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on 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).

In addition, we request that you submit all reported medication errors, including potential medication errors and those that resulted in no adverse event or a non-serious adverse event, and reported complaints surrounding conversion of units between botulinum toxin products, as part of the periodic Safety Update Reports (PSURs).

If you have any questions, call Karen Abraham-Burrell, PharmD, Regulatory Project Manager, at (301) 796-2721.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

RUSSELL G KATZ
05/22/2012