DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125360/S-040

SUPPLEMENT BLA APPROVAL
REMS ASSESSMENT ACKNOWLEDGMENT
RELEASE REMS REQUIREMENT

Merz Pharmaceuticals, LLC
Attention: Jason C. Mercer, Ph.D., RAC
Regulatory Affairs Manager
4215 Tudor Lane
Greensboro, NC 27410

Dear Dr. Mercer:

Please refer to your Supplemental Biologics License Application (sBLA), dated June 8, 2012, received June 8, 2012, submitted under section 351 of the Public Health Service Act for Xeomin (incobotulinumtoxinA).

We acknowledge receipt of your email correspondence dated June 4, 2012. We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated February 1, 2012. 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 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.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Xeomin (incobotulinumtoxinA) was originally approved on July 30, 2010, and the most recent REMS modification was approved on July 20, 2011. 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 Xeomin (incobotulinumtoxinA) 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 Xeomin (incobotulinumtoxinA).

We remind you that the Medication Guide will continue to be part of the approved labeling for Xeomin (incobotulinumtoxinA) 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
07/16/2012