BLA 125360/S-087
BLA 125360/S-088
BLA 125360/S-089
BLA 125360/S-090
BLA 125360/S-091

SUPPLEMENT APPROVAL

Merz Pharmaceuticals GmbH
Attention: Hadley Iliff, MA, MBA
Director, US Regulatory Affairs
6501 Six Forks Road
Raleigh, NC 27615

Dear Ms. Iliff:

Please refer to your supplemental biologics license applications (sBLAs), and your amendments, submitted under section 351(a) of the Public Health Service Act for the following:

BLA Number/ Supplement Number	Drug Product	Submitted on:	Received on:
BLA 125360/S-087	Xeomin (incobotulinumtoxinA) injection	October 19, 2020	October 19, 2020
BLA 125360/S-088			
BLA 125360/S-089			
BLA 125360/S-090		October 20, 2020	October 20, 2020
BLA 125360/S-091			

These Prior Approval supplemental biologics applications provide for the following:

BLA Number/ Supplement Number	Modification
BLA 125360/S-087	Modifications to Subsection 8.4 of the Prescribing Information (PI) under the Juvenile Animal Toxicity Data heading
BLA 125360/S-088	Replacement of the anatomical figure in Subsection 2.3 of the PI
BLA 125360/S-089	1. Modifications to the Highlights section related to Dosage and Administration; 2. Replacement of the anatomical figure in Subsection 2.5; and, 3. Modifications to the text in Subsection 2.5.

BLA 125360/S-090	1. Modifications to the Highlights section related to Dosage and Administration; 2. Replacement of the anatomical figure in Subsection 2.4; and, 3. Modifications to the text in Subsection 2.4.
BLA 125360/S-091	Replacement of the injection sites figure for the indication of glabellar lines in Subsection 2.6 of the PI

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF HIGHLIGHTS ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information) 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes 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 Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

your submission(s), 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).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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).

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, contact Taura Holmes, PharmD, MS, Senior Regulatory Project Manager, at Taura.Holmes@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Eric Bastings, MD
Director (Acting)
Division of Neurology 1
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ERIC P BASTINGS
04/19/2021 07:46:00 PM