BLA 103000/S-5325

CORRECTED SUPPLEMENT APPROVAL
CORRECTED FULFILLMENT OF POSTMARKETING REQUIREMENT

Allergan, Inc.
Attention: Claire Whitley, BSc (Hons) Int.
Senior Director Global Therapeutic Area Head
Therapeutic Neurotoxins, Regulatory Affairs
2525 Dupont Drive, AND200A
Irvine, CA 92612

Dear Claire Whitley:

Please refer to your supplemental biologics license application (sBLA), dated and received October 14, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Botox (onabotulinumtoxinA) for injection.

We also refer to our approval letter dated August 11, 2023, which contained the following error: The Package Insert did not contain “Mephisto sign” in Section 6.3.

This corrected action letter incorporates the correction of the error. The effective action date will remain August 11, 2023, the date of the original letter.

This Prior Approval supplemental biologics license application provides for changes in the Package Insert requesting incorporation of new pediatric overactive bladder (OAB) data submitted from Study 191622-137.

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 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 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 *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 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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.

We note that you have fulfilled the pediatric studies requirement for ages 12 to 17 years for this supplemental application.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated April 10, 2020, containing the final reports for the following postmarketing requirement listed in the October 13, 2013, post-approval postmarketing requirement letter for BLA 103000/S-5251.

[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.

- 2724-3, the merged protocol Study 191622-137, was developed from the pediatric protocol Study 191622-137 (initial study) and Study 191622-138 (long-term extension study), i.e., the originally submitted Post Marketing Required studies per the OAB (sBLA 103000/5251) Approval Letter, dated January 18, 2013. As discussed in the correspondence between the Agency and Allergan on July 16 and 17, 2013, this merger is administrative and intended to make study conduct more efficient for the physicians, patients, and IRB/ethics committees.

We have reviewed your submission and conclude the above requirements were fulfilled.

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 athttps://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, please call Nenita Crisostomo, RN, Regulatory Health Project Manager, at 301-796-0875.

Sincerely,

{See appended electronic signature page}

Catherine Pilgrim-Grayson, M.D., M.P.H.
Deputy Director for Safety
Division of Urology, Obstetrics, and Gynecology
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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/

CATHERINE A PILGRIM-GRAYSON
08/16/2023 05:21:38 PM