BLA 125274/S-123

GENERAL ADVICE

Ipsen Biopharm Limited
Attention: Diego Gualteros
Director, Global Regulatory Affairs, Neuroscience
One Main Street, 7th Floor
Cambridge, MA 02142

Dear Mr. Gualteros:[1]

Please refer to your supplemental Biologics License Application (sBLA) under section 351(a) of the Public Health Service Act for Dysport (abobotulinumtoxinA) injection.

We also refer to our approval letter dated January 12, 2023.

Further, we acknowledge receipt of your January 20, 2023, email correspondence noting that our January 12, 2023, approval letter contained the following errors on Figure 2 of the prescribing information: (1) deletion of the borders and (2) inaccurate resizing.

This general advice letter provides for the replacement of Figure 2 in the prescribing information.

[1] 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.

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}

Teresa Buracchio, MD
Director
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/

TERESA J BURACCHIO
01/27/2023 12:05:21 PM

BLA 125274/S-123

SUPPLEMENT APPROVAL

Ipsen Biopharmaceuticals, Inc.
o/b/o Ipsen Biopharm Limited
Attention: Diego Gualteros, Director, Global Regulatory Affairs
One Main Street, 7th floor
Cambridge, MA 02142

Dear Mr. Gualteros:

Please refer to your supplemental biologics license application (sBLA), dated March 8, 2022, received March 8, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Dysport (abobotulinumtoxinA) injection.

This Prior Approval sBLA provides for the following changes to the Dosage and Administration section of the Dysport Prescribing Information:

1. Addition of ultrasound as a guidance technique for the administration of Dysport, and

2. Adjustment in language for the vial vacuum.

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 Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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).

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).

[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.
[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}

Teresa Buracchio, MD
Director
Division of Neurology 1
Office of Neuroscience
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ENCLOSURE:

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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/s/

TERESA J BURACCHIO
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