NDA 20807 00

**SUPPLEMENT APPROVAL**

Primus P armaceuticals, Inc. h
Attention: Kat ryn Coressel
Regulatory Consultant
10860 W. 8 t Ave.
Arvada, CO 80005

Dear Kat ryn Coressel:

Please refer to your supplemental new drug application (sNDA) dated and received April , 2025, submitted pursuant to section 505(b)(2) of t e Federal Food, Drug, and Cosmetic Act (FDCA) for ernivo (betamet asone dipropionate) topical spray.

T is Prior Approval sNDA provides for co packaging of ernivo (betamet asone dipropionate) topical spray, 0.05% wit a telescopic medical device as a combination product.

## APPROVAL & LABELING

We ave completed our review of t is application, as amended. It is approved, effective on t e date of t is letter, for use as recommended in t e enclosed agreed upon labeling wit minor editorial revisions listed below and reflected in t e enclosed labeling.

- A orizontal line between Hig lig ts and t e TOC and between t e TOC and FPI.
- Vertical lines in t e left margin of subsections 2.1 and 2.2 to indicate t e recent major c anges.

## CONTENT OF LABELING

As soon as possible, but no later t an 1 days from t e date of t is letter, submit t e content of labeling [21 CFR 31 .50(l)] in structured product labeling ( PL) format using t e FDA automated drug registration and listing system (eLI T), as described at FDA.gov.[1] Content of labeling must be identical to t e enclosed labeling (text for t e Prescribing Information, Patient Package Insert, Instructions for Use, wit t e addition of any labeling c anges in pending “C anges Being Effected” (CBE) supplements, as well h as annual reportable c anges not included in t e enclosed labeling.

[1] ttp: www.fda.gov ForIndustry Data tandards tructuredProductLabeling default. tm h

Information on submitting PL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As.*[2]

The PL will be accessible from publicly available labeling repositories.

Also within 1 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 31 .50(l)(1)(i)] 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, 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).

## CARTON AND CONTAINER LABELING

ubmit final printed carton and device bag labeling that are identical to the enclosed carton and device bag labeling, except with the revisions listed below, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – F nal Pr nted Carton and Conta ner Label ng for approved NDA 208079/ S-004**." Approval of this submission by FDA is not required before the labeling is used.

- Update: Telescopic Medical Device Co Package date to 0 2025
- Update: Telescopic Device Bag Label date to 0 2025

## 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 in Materials for Human Prescription Drugs*.[3] **i**

[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 athttps: www.fda.gov media 128163 download. **i**

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 31 .81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov. Information and Instructions for completing the form can be found at FDA.gov.[5]

## PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 31 .53(d)(2) and 31 .70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 31 .53(d)(2)(i)(A) through (C) and 31 .53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 35 2 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 31 .53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 31 .53(d)(2)(ii)(B) and 31 .53(f)(2)(iv).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR , ubpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.[6]

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 31 .80 and 31 .81.

## COMPENDIAL STANDARDS

A drug with a name recognized in the official United tates Pharmacopeia or official National Formulary (U P NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 U C 351(b)). FDA typically cannot share application specific information contained in submitted regulatory filings with third parties, which includes U P NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with U P NF to revise official U P monographs. More information on the U P NF is available on U P's website[7].

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http www.fda.gov downloads AboutFDA ReportsManualsForms Forms UCM083570.pdf

[5] http: www.fda.gov downloads AboutFDA ReportsManualsForms Forms UCM37515 .pdf

[6] https: www.fda.gov combination products guidance regulatory information postmarketing safety reporting combination products

[7] https: www.uspnf.com /

If you have any questions, contact ascha Randolph, Regulatory Project Manager, at ascha.Randolph@fda.hhs.gov.

incerely,

*{See appended electronic signature page}*

Tatiana Oussova, MD, MPH
Deputy Director for afety
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLO SURE( ):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use
- Carton and Device Bag Labeling

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**This is a r r s a i f a O l c r ic r c rd ha was sig d l c r ically. F ll wi g his ar ma if s a i s f a y a d all l c r ic sig a ur s f r his l c r ic r c rd.**

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/s/ O

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