NDA 209478/S-003

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

CMP Development, LLC
Attention: Ellen Barkley
Regulatory Affairs Manager
PO Box 147
8026 US Highway 264A
Farmville, NC 27828

Dear Ms. Barkley:

Please refer to your supplemental new drug application (sNDA) dated and received May 27, 2021, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Carospir (spironolactone) Oral Suspension.

This "Prior Approval" supplemental new drug application provides for updates to include language regarding a drug-drug interaction with digoxin and language regarding CYP2C8 and CYP3A substrates. The following labeling sections were affected: Drug Interactions (7.4, 7.7) and Clinical Pharmacology (12.3).

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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]

[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.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 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 314.50(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(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).

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

We received your submission dated July 12, 2019, reporting on in vivo drug-drug interaction and reaction phenotyping study reports and your April 29, 2019 submission containing the final report for the following postmarketing requirement listed in the September 4, 2017 approval letter.

3256-3 Conduct a clinical drug-drug interaction trial to evaluate a potential interaction between digoxin and spironolactone using a validated analytical method to quantify plasma digoxin levels.

Final Protocol Submission:	03/2018
Study Completion:	09/2018
Final Report Submission:	03/2019

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there are postmarketing requirements that are still open.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Lori Anne Wachter, RN, BSN, RAC
Regulatory Project Manager for Safety
301 796-3975

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology, Endocrinology and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE(S):

- 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/

MARY R SOUTHWORTH
06/25/2021 03:18:57 PM