NDA 017116/S-043

CORRECTED SUPPLEMENT APPROVAL

SpecGx LLC
385 Marshall Avenue
Webster Groves, MO 63119

Attention: Shara Ambrosecchia, MS, RAC
Associate Director, Regulatory Affairs

Dear Ms. Ambrosecchia:

Please refer to your supplemental new drug application (sNDA) dated and received July 1, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Methadose (methadone hydrochloride) oral concentrate.

This Prior Approval sNDA proposes conversion of the content of the currently approved prescribing information into the Physician Labeling Rule (PLR) format as set forth under 21 CFR 201.56 and 21 CFR 201.57.

We also refer to our Supplement Approval letter dated September 13, 2021, which contained the following errors: the HIGHLIGHTS OF PRESCRIBING INFORMATION, DOSAGE FORMS AND STRENGTHS, DESCRIPTION, and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information contained the incorrect dosage form.

This corrected action letter incorporates the correction of the error. The effective action will remain September 13, 2021, the date of the original letter.

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.

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

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

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]

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).

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, call Sandy Truong, Regulatory Project Manager, at 301-796-5719.

Sincerely,

{See appended electronic signature page}

Rigoberto Roca, MD
Director
Division of Anesthesiology, Addiction Medicine, and Pain Medicine
Office of Neursocience
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

[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.

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/

RIGOBERTO A ROCA
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