NDA 017386/S-043

APPROVAL LETTER

Lannett Company Inc
Attention: Kristie Stephens
Vice President of Regulatory Affairs
9000 State Road
Philadelphia, PA 19136

Dear Ms. Stephens:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 30, 2019, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zaroxolyn (metolazone) Tablets, 2.5 mg, 5 mg, and 10 mg.

This Prior Approval supplemental new drug application provides for changes to the drug product dissolution specification/method & replacing the D&C Red #33 Aluminum Lake, used in 2.5 mg tablets, with Lake Blend LB-140024 Pink Dye.

APPROVAL & LABELING

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

Additional Comments

We recommend the following be implemented at next printing:

Container Labels

- Revise the statement "DO NOT INTERCHANGE: … should not be interchanged (see package circular)" to read "DO NOT SUBSTITUTE:… should not be substituted (see prescribing information)".
- Revise the statement "INDICATIONS & DOSAGE: See package circular" to read "DOSAGE: See prescribing information".
- In September 2018, FDA released draft guidance on product identifiers required under the Drug Supply Chain Security Act.[a] The Act requires manufacturers and repackagers, respectively, to affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction in(to) commerce beginning November 27, 2017, and November 27, 2018, respectively. We recommend that you review the draft guidance to determine if the product identifier requirements apply to your product's labeling. The product identifier contains the NDC, serial number, lot, and expiration date. The DSCSA guidance on product identifiers recommends the format below for the human-readable portion of the product identifier. The

guidance also recommends that the human-readable portion be located near the 2D data matrix barcode.

NDC: [insert product's NDC]
SERIAL: [insert product's serial number]
LOT: [insert product's lot number]
EXP: [insert product's expiration date]

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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 titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. 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 IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels and carton and immediate container labels submitted on January 30, 2019, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and**

Container Labels for approved NDA 017386/S-043." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Abolade (Bola) Adeolu, Regulatory Business Process Manager, at (301) 796 - 4264.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, PhD
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Carton and Container Labeling