NDA 210566/S-005

SUPPLEMENT APPROVAL

Mayne Pharma LLC
Attention: Kelly Delgado
Manager, Regulatory Affairs
1240 Sugg Parkway
Greenville, NC 27834

Dear Kelly Delgado:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 20, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lexette (halobetasol propionate) Foam.

This "Changes Being Effected" supplemental new drug application provides for changes to the primary and secondary container labels to include the statement **"IMPORTANT: Shake well before each application and turn can completely upside down to dispense**".

APPROVAL & LABELING

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

Revise the first sentence in section 2 of the LEXETTE® United States Package Insert (Dosage and Administration) from "Shake can prior to use" to "shake can prior to use and turn can completely upside down to dispense" in order to harmonize dispensing instructions between the professional labeling, the container and carton labels, and the patient information leaflet.

CARTON AND CONTAINER LABELS

We acknowledge your January 20, 2022, submission containing final printed carton and container labeling.

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 Adlaide Addo, Regulatory Business Process Manager, at (301) 796 - 6923.

Sincerely,

{See appended electronic signature page}

David B. Lewis, Ph.D.
Branch Chief, B2
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
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