DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 017874/S-042

APPROVAL LETTER

GlaxoSmithKline Consumer Health (GSK)
Attention: Gregory Seitz
Executive Director Regulatory Affairs
100 College Road West
Princeton, New Jersey 08540

Dear Mr. Seitz:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 9, 2017, and your amendments submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Transderm Scop® (scopolamine) Transdermal System, 1.5 mg.

This Prior Approval supplemental new drug application provides for provides for fulfillment of the commitment made by the applicant to the agency, on May 7, 2013, to imprint the product name and strength on the backing of the Transderm Scop® (scopolamine) Transdermal System.

We have completed our review of this supplemental application, as amended, it is **approved.**

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 package insert, text for the patient package insert, Medication Guide), 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 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 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).

REPORTING REQUIREMENTS

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

If you have any questions, call Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402-1773

Sincerely,

{See appended electronic signature page}

David B. Lewis, Ph.D.
Branch II Chief (acting)
Division of Postmarketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling

David
Lewis

Digitally signed by David Lewis
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