DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018827/S-046

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
Attention: Peter Maybo
Associate Director, Regulatory Affairs International-HQ
351 N. Sumneytown Pike, P.O. Box 1000
UG2C-50
North Wales, PA 19454-2505

Dear Mr. Maybo:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 23, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for LOTRISONE (clotrimazole and betamethasone dipropionate) cream, 1%/0.05%.

We acknowledge receipt of your amendments dated July 12 and September 6, 2013; February 21 and 28, March 7 and 17, and April 11, 2014.

This "Prior Approval" supplemental new drug application provides for labeling revisions to conform to the new labeling content and format requirements for human prescription drug and biological products according to 21 CFR 201.56(d) and 201.57.

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 and with the minor editorial revisions listed below.

1. Highlights (HL) should have ½ inch margins on all sides and between columns. Change the top and bottom margins to ½ inch.

2. There is a horizontal line that separates the Table of Contents (TOC) from the Full Prescribing Information (FPI) at the bottom of the TOC on the first page of the labeling. However, there is another horizontal line at the top of the second page of the labeling above the FULL PRESCRIBING INFORMATION heading. There should only be one horizontal line that separates the TOC from the FPI, not two horizontal lines. Delete the horizontal line at the top of the second page of the labeling.

3. The section and subsection headings in the TOC must match the section and subsection headings in the FPI. Subsection headings 6.1 Clinical Trials Experience and 6.2

Postmarketing Experience appear in the FPI but are missing from the TOC. Include subsection headings 6.1 and 6.2 in the TOC.

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, except with the revisions listed, the enclosed labeling (text for the package insert, text for the patient package insert), 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 includes 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 with the revisions listed above 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 the enclosed carton and immediate container labels and carton and immediate-container labels submitted on March 17, 2014, 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 (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 018827/S-046**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Matthew White, Regulatory Project Manager, at (301) 796-4997.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

TATIANA OUSSOVA
04/21/2014