



NDA 019116/S-009

**SUPPLEMENT APPROVAL**

PreCISION Dermatology, Inc., a division of Valeant Pharmaceuticals North America, LLC  
Attention: Sean Humphrey  
Manager, Regulatory Affairs  
400 Somerset Corporate Blvd.  
Bridgewater, NJ 08807

Dear Mr. Humphrey:

Please refer to your supplemental New Drug Application (sNDA) dated May 7, 2014, received May 9, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Locoid<sup>®</sup> (hydrocortisone butyrate) Solution, 0.1%.

We acknowledge receipt of your amendments dated June 19; September 8, and 12; and October 1, and 20, 2014.

This "Prior Approval" supplemental new drug application proposes the following changes to the labeling:

1. Incorporation of the results of the 2-year dermal rat carcinogenicity study conducted with Locoid<sup>®</sup> Lotion, 0.1%
2. Editorial changes for consistency with other Locoid labeling
3. Revision of the NDC number, contact and manufacturer information

**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.

**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) submitted on October 20, 2014, 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 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, submitted on September 12, 2014.

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 019116/S-009.**” 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.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

**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 Belainesh Robnett, Regulatory Project Manager, at (240) 402-4236.

Sincerely,

*{See appended electronic signature page}*

Tatiana Oussova, MD, MPH  
Acting Director  
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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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TATIANA OUSSOVA  
10/30/2014