



NDA 022129/S-005

**SUPPLEMENT APPROVAL**

Shionogi Inc.  
Attention: Lisa LeSueur  
Senior Manager, Regulatory Affairs  
300 Campus Drive  
Suite 300  
Florham Park, NJ 07932

Dear Ms. LeSueur:

Please refer to your Supplemental New Drug Application (sNDA) dated January 20, 2012 received January 23, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ulesfia™ (benzyl alcohol) Lotion, 5%.

We acknowledge receipt of your amendments dated May 25, June 13, 18 and 26, and July 5, 2012.

This "Prior Approval" supplemental new drug application provides for the following:

- A two-bottle unit of use carton of Ulesfia™ 8-ounce bottles.
- Inclusion of a nit comb, a Class I exempt medical device, in the two-bottle carton
- Minor editorial changes to the package insert and carton/container labels

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.

- In Highlights of Prescribing Information under **RECENT MAJOR CHANGES**, the date of the recent major change was right justified and the dashes were deleted.

**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 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 container labels that are identical to the enclosed carton and immediate container labels 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 titled “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 “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 022129/S-005.**” Approval of this submission by FDA is not required before the labeling is used.

### **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}*

Stanka Kukich, MD  
Deputy Director

Division of Dermatology and Dental Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

ENCLOSURE(S):

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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STANKA KUKICH  
07/12/2012