



NDA 21-717/S-002

Galderma Laboratories, L.P.  
14501 North Freeway  
Fort Worth, TX 76177

Attention: Paul M. Clark  
Director, Regulatory Affairs

Dear Mr. Clark:

Please refer to your supplemental new drug application dated January 19, 2007, received January 23, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pliaglis™ (lidocaine and tetracaine) Cream 7% / 7%.

This “Changes Being Effected” supplemental new drug application provides for revisions to the package insert, carton labeling and container labeling in response to our December 26, 2006, supplement request letter.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling (text for package insert, immediate container and carton labels) and with one minor editorial revision: correct the misspelling of “prescribing” on the container label.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text for the package insert. For administrative purposes, designate this submission as “**Content of Labeling for Approved NDA 21-717/S-002.**” Upon receipt and verification that the content of labeling in SPL format is identical to the approved labeling text, we will transmit that version to the National Library of Medicine for public dissemination.

Please electronically submit final printed carton and container labels that are identical (except for the editorial revision requested above) to the enclosed carton and immediate container labels submitted January 19, 2007. Alternatively, you may submit 12 paper copies of the carton and container labels as soon as they are available but no more than 30 days after they are printed. Individually mount 6 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 21-717/S-002.**” Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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, contact Geri Smith, Regulatory Project Manager, at [geri.smith@fda.hhs.gov](mailto:geri.smith@fda.hhs.gov) or (301) 796-2204.

Sincerely,

*{See appended electronic signature page}*

Bob Rappaport, M.D.  
Director  
Division of Anesthesia, Analgesia and  
Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosures: Carton Label  
Container Label  
Package Insert

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Bob Rappaport  
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