

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

050803Orig1s000

APPROVAL LETTER



NDA 050803

NDA APPROVAL

Stiefel, a GSK company
Attention: Susanne Wilhelm, M.S., R.A.C.
Associate Director, Regulatory Affairs
20 TW Alexander Drive
Research Triangle Park, NC 27709

Dear Ms. Wilhelm:

Please refer to your New Drug Application (NDA) dated August 23, 2004, received August 25, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Veltin (clindamycin phosphate and tretinoin) Gel, 1.2%/0.025%.

We acknowledge receipt of your amendments dated September 30, October 5, 8, 15, and 28, November 17, 19 and 22, and December 6, 2004; January 7 and 28, February 11 and 17, March 2 (2), 4, 8, 14, 22, and 25, April 5, 8, 14, and 22, May 4, 12, 16 and 17, June 9, and 15 (2), July 15 and 22, and August 22 and 26, 2005; April 13, 2006; January 9, 2007; March 27, 2008; October 15, November 6, 10, 23 and 25, and December 21, 2009; January 15 and 21, February 11 and 15, March 9, 11, 16 and 18, May 3, 4, 5 and 28, June 14 and 23, and July 9 and 15, 2010.

The October 15, 2009 submission constituted a complete response to our June 10, 2005 action letter.

This new drug application provides for the use of Veltin (clindamycin phosphate and tretinoin) Gel, 1.2%/0.025% for the topical treatment of acne vulgaris.

We have completed our review of this 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, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert). 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

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 (October 2005)”. 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 050803.**” Approval of this submission by FDA is not required before the labeling is used.

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

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

Please submit one market package of the drug product when it is available.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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 Cristina Attinello, Regulatory Project Manager, at (301) 796-3986.

Sincerely,

{See appended electronic signature page}

Susan J. Walker, M.D., F.A.A.D.
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

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-50803

ORIG-1

STIEFEL A GSK CO Veltin

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

/s/

SUSAN J WALKER

07/16/2010