



NDA 050741/S-26

SUPPLEMENT APPROVAL

Stiefel Laboratories, Inc.
c/o GlaxoSmithKline
1250 South Collegeville Road
PO Box 5089, Mail Code UP4400
Collegeville, PA 19426-0989

Attention: Linda Rebar
Director, Global Regulatory Affairs

Please refer to your supplemental new drug application (sNDA) dated and received April 23, 2020, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Duac (benzoyl peroxide and clindamycin phosphate) gel.

This prior approval sNDA provides for the following:

- Updates to be consistent with the Pregnancy and Lactation Labeling Rule. Included a new statement in the *Pregnancy* subsection that available data over decades of use with DUAC and other topical clindamycin and benzoyl peroxide products in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes.
- Updated statements in the labeling to improve the clarity of the information. For example, used a consistent method for incorporating the required elements into each warning in the WARNINGS AND PRECAUTIONS section (i.e., directives to healthcare providers followed by the description of the clinically significant adverse reaction or risk).
- Updates to the PATIENT COUNSELING INFORMATION section to be consistent with the recommendations in the guidance for industry: *Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products – Content and Format*^{1,2} (December 2014).
- Updates to the information in the Patient Package Insert to be consistent with the changes in the U.S. Prescribing Information and to improve the format and readability of information.

¹ <https://www.fda.gov/media/86734/download>

² We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>

APPROVAL & LABELING

We have completed our review of this sNDA. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 FDA.gov.³ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, and 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 guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.

The SPL will be accessible from publicly available labeling repositories. Also within 14 days, amend all pending supplemental applications that include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

³ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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, contact Emilija Renke, Regulatory Project Manager, at Emilija.Renke@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Gary Chiang, MD, MPH
Acting Associate Director for Therapeutic Review
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling

- Prescribing Information
- Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

GARY T CHIANG
10/07/2026 10:18:09 AM