



ANDA 211827

**ANDA APPROVAL**

Teva Pharmaceuticals USA, Inc.  
577 Chipeta Way  
Salt Lake City, UT 84108  
Attention: Cherri Petrie  
Senior Director, Regulatory Affairs

Dear Madam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 6, 2018, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Efinaconazole Topical Solution, 10%.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the tentative approval letter issued by this office on October 16, 2019, the complete response letter issued by this office on September 9, 2020, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly, the ANDA is **approved**, effective on the date of this letter. We have determined your Efinaconazole Topical Solution, 10%, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Jublia Topical Solution, 10%, of Bausch Health Americas, Inc. (Bausch).

The RLD upon which you have based your ANDA, Bausch's Jublia Topical Solution, 10%, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
7,214,506 (the '506 patent)	October 5, 2021
8,039,494 (the '494 patent)	July 8, 2030
8,486,978 (the '978 patent)	October 24, 2030

9,302,009 (the '009 patent)	October 24, 2030
9,566,272 (the '272 patent)	January 3, 2028
9,662,394 (the '394 patent)	October 2, 2034
9,861,698 (the '698 patent)	July 8, 2030
9,877,955 (the '955 patent)	January 3, 2028
10,105,444 (the '444 patent)	July 8, 2030
10,342,875 (the '875 patent)	October 2, 2034
10,478,601 (the '601 patent)	April 25, 2035
10,512,640 (the '640 patent)	January 3, 2028
10,828,293 (the '293 patent)	October 2, 2034
10,828,369 (the '369 patent)	January 3, 2028

Your ANDA contains paragraph IV certifications to each of the patents<sup>1</sup> under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Efinaconazole Topical Solution, 10%, under this ANDA. You have notified the Agency that Teva Pharmaceuticals USA, Inc. (Teva) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Teva for infringement of the '506, '494, '978, '009, '272, '394, '698, and '955 patents in the United States District Court for the District of New Jersey [Valeant Pharmaceuticals North America LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al., Civil Action No. 18-13635 (consolidated)]. You have also notified the Agency that, on November 25, 2019, the court entered a Stipulated Consent Judgment and Injunction, which terminated the 7.5-year period provided for in sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the FD&C Act.

With respect to 180-day patent challenge exclusivity under section 505(j)(5)(B)(iv) of the FD&C Act, we note that Teva was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Efinaconazole Topical Solution, 10%. Therefore, with this approval, Teva is eligible for 180 days of shared generic drug exclusivity for Efinaconazole Topical Solution, 10%. FDA notes that after issuance of this approval letter, eligibility for 180-day exclusivity is subject to future events that may result in forfeiture of exclusivity under section 505(j)(5)(D) of the FD&C Act. This patent challenge exclusivity will begin to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first

commercial marketing of this drug product or the RLD. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

We note that Teva was granted a Competitive Generic Therapy (CGT) designation for Efinaconazole Topical Solution, 10%. However, as noted in the June 1, 2018 CGT Designation – Grant Letter, your drug product is not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act because there were unexpired patents or exclusivities listed in FDA's Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book) for the RLD at the time of submission of your ANDA. Teva is also not a "first approved applicant" for such competitive generic therapy, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

## **REPORTING REQUIREMENTS**

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts; therefore, we remind you that you must comply with the postmarketing safety reporting requirements for an approved combination product (21 CFR Part 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. 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 (PI), Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

You must also submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **ANNUAL FACILITY FEES**

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions<sup>2</sup> with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1<sup>st</sup> of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the *Federal Register* notice announcing facility fee amounts.

All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, using 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 in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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 <https://www.fda.gov/media/71211/download>. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

*{See appended electronic signature page}*

For Edward M. Sherwood  
Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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<sup>1</sup> The Agency notes that the '444, '875, '601, '640, 293, and 369 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

<sup>2</sup> Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).



John  
Ibrahim

Digitally signed by John Ibrahim

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