CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

204427Orig1s000

Trade Name:	Kerydin topical solution, 5%
Generic Name:	Tavaborole
Sponsor:	Anacor Pharmaceuticals, Inc.
Approval Date:	July 7, 2013
Indications:	For the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes.*

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APPROVAL LETTER

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204427

NDA APPROVAL

Anacor Pharmaceuticals, Inc.
Attention: Carmen Rodriguez, MSc
Vice President, Regulatory Affairs and Quality
1020 East Meadow Circle
Palo Alto, CA 94309-4320

Dear Ms. Rodriguez:

Please refer to your New Drug Application (NDA) dated July 26, 2013, received July 29, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kerydin (tavaborole) topical solution, 5%.

We acknowledge receipt of your amendments dated August 9, 14 and 19, October 18, 23 and 30, November 18 and 25, and December 19 and 27, 2013: January 16, 21 and 31, April 1, 4 and 18, May 5, 13 and 20, and June 2, 11 and 23, 2014.

This new drug application provides for the use of Kerydin (tavaborole) topical solution, 5% for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes.*

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 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 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 *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

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CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate 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 *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 **"Final Printed Carton and Container Labels for approved NDA 204427."** Approval of this submission by FDA is not required before the labeling is used.

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

ADVISORY COMMITTEE

Your application for (tavaborole) topical solution, 5% was not referred to an FDA advisory committee because outside expertise was not necessary; there were no controversial issues that would benefit from advisory committee discussion.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indications in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 11 years and 11 months because necessary studies are impossible or highly impracticable. This is because onychomycosis due to *Trichophyton rubrum* or *Trichophyton mentagrophytes* is not prevalent in the population younger than 12 years of age.

We are deferring submission of your pediatric study for ages 12 to 17 years and 11 months for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

PMR 2154-1 Pharmacokinetic/safety study of tavaborole topical solution, 5% in 40 pediatric subjects age 12 to 17 years and 11 months with onychomycosis of the toenails.

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