DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-070 **NDA APPROVAL**

Coria Laboratories, Ltd.
Attention: Amy Campbell, Regulatory Affairs Manager
3909 Hulen Street
Fort Worth, TX 76107

Dear Ms. Campbell:

Please refer to your new drug application (NDA) dated September 27, 2006, received September 28, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Atralin (tretinoin) Gel, 0.05%.

We acknowledge receipt of your submissions dated January 5, February 12 and 19, March 30, May 3 and 7, June 5, 20 and 27, and July 3, 2007.

This new drug application provides for the use of Atralin (tretinoin) Gel, 0.05% 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, please submit the 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 to the enclosed labeling (text for the package insert and text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-070."

## 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 22-070**." 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.

## PEDIATRIC RESEARCH EQUITY ACT (PREA)

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for patients 12 years of age and younger for this application. We note that you have fulfilled the pediatric study requirement for this application for patients over the age of 12.

## POSTMARKETING COMMITMENTS

We remind you of your postmarketing study commitments in your submissions dated July 23 and 24, 2007. These commitments are listed below.

1. Description of Commitment:
   Mouse dermal carcinogenicity study
   Protocol Submission: by 12/08
   Study Start: by 08/09
   Final Report Submission: by 08/12

2. Description of Commitment:
   A dermal safety study to assess cumulative irritancy from Atralin Gel 0.05%, using the final, to-be-marketed formulation
   Protocol Submission: received 05/07
   Study Start: ongoing, began 05/07
   Final Report Submission: by 10/07

3. Description of Commitment:

A dermal safety study to fully assess photoallergy and phototoxicity from Atralin Gel 0.05%, using the final, to-be-marketed formulation. This should include 50 evaluable subjects for the photoallergy and 30 evaluable subjects for the phototoxicity studies

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| Protocol Submission: | by 10/07 |
| Study Start: | by 11/07 |
| Final Report Submission: | by 03/08 |

Submit the protocols to your IND for this product and the study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of the commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates and any changes in plans since the last annual report. All submissions, including supplements, relating to this postmarketing study commitment should be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

## 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(s) 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(s), 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 www.fda.gov/cder/ddmac.

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 Melinda Bauerlien, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

*{See appended electronic signature page}*

Susan J. Walker, M.D., F.A.A.D.
Director
Division of Dermatology & Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

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/s/

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Susan Walker
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