DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-769/S-011 **SUPPLEMENT APPROVAL**

Triax Pharmaceuticals
Attention: Kathryn Bishburg, Pharm.D.
Executive Director, Regulatory Affairs
11 Commerce Drive, Suite 100
Cranford, NJ 07016

Dear Dr. Bishburg:

Please refer to your supplemental new drug application dated December 18, 2008, received December 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Locoid Lipocream (hydrocortisone butyrate) Cream, 0.1%.

We acknowledge receipt of your submissions dated January 29, February 3, May 21, July 1, September 3, October 6, and October 19, 2009.

This "Prior Approval" supplemental new drug application provides for the use of Locoid Lipocream (hydrocortisone butyrate) Cream, 0.1% for treatment of mild to moderate atopic dermatitis in patients 3 months of age to less than 18 years of age.

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 and with the following agreed upon editorial changes to the carton and immediate container labels:

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)

or if space is limited

Store at 25°C (77°F) (see insert)

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)(1)(i)] 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). For administrative purposes, please designate this submission, "**SPL for approved NDA 20-769/S-011**".

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels, except with the revisions listed above, 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 20-769/S-011**." Approval of this submission by FDA is not required before the labeling is used.

POSTMARKETING COMMITMENTS

We acknowledge your written commitment to conduct the following postmarketing study as described in your submission dated October 19, 2009, and as outlined below:

1557-1. Evaluate the relative potency ranking of Locoid Lipocream as compared to Locoid Lotion using an adequate single point vasoconstrictor assay study. Vasoconstrictor data should be submitted for the two Locoid formulations and comparator products with different potency rankings (i.e. high, medium and low) that allow for the bracketing of the potency response of the Locoid Lipocream and Locoid lotion. The comparators selected must include Temovate cream and Diprolene AF cream due to the inconclusive data potency ranking data that was obtained with these two comparators in your previous studies (protocol No. 94-MCK-04 and protocol No. 01-036) that were submitted in NDA 20-769 and NDA 22-076 respectively. Evaluation of vasoconstriction should be done by a trained observer/primary investigator according to a standardized ranking procedure.

Protocol Submission:	by 12/09
Study Start:	by 02/10
Study Completion:	by 04/10
Final Report Submission:	by 06/10

Submit the protocol to your IND for this product, with a cross-reference letter to this NDA. Submit the final report to your NDA. Use the following designators to prominently label all submissions, including supplements, relating to this postmarketing study commitment, as appropriate:

- **POSTMARKETING STUDY COMMITMENT PROTOCOL**
- **POSTMARKETING STUDY COMMITMENT FINAL REPORT**
- **POSTMARKETING STUDY COMMITMENT CORRESPONDENCE**

In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study.

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 http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
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 Paul Phillips, Regulatory Project Manager, at (301) 796-3935.

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 Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20769	SUPPL-11	TRIAX PHARMACEUTICALS LLC	LOCOID LIPOCREAM

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
10/19/2009