DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18031/S-036 **SUPPLEMENT APPROVAL**

Akrimax Pharmaceuticals, LLC
Attention: Kathryn Bishburg, Pharm.D.
11 Commerce Drive, Suite 100
Cranford, NJ 07016

Dear Dr. Bishburg:

Please refer to your supplemental new drug application dated November 25, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Inderide, (propranolol HCl/hydrochlorothiazide) 40/25, and 80/25 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the **WARNINGS** and **ADVERSE REACTIONS** section of the package insert:

1. Under **WARNINGS, Propranolol hydrochloride**, the words "and hydrochlorothiazide" was added at the end of the paragraph.

2. Under **ADVERSE REACTIONS, Hydrochlorothiazide, *Skin***, the phrase, "Erythema multiforme including Steven-Johnson syndrome, exfoliative dermatitis, including toxic epidermal necrolysis" was added.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on November 25, 2009.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

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

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. 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, please call:

Lori Wachter, RN, BSN
Regulatory Health Project Manager
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure:
Approved labeling text

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-18031	SUPPL-36	AKRIMAX PHARMACEUTICALS LLC	INDERIDE-40/25

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

/s/

MARY R SOUTHWORTH
03/04/2010