DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-418/S-079

Akrimax Pharmaceuticals
ATTENTION: Kathryn Bishburg, Pharm.D.
20 Commerce Drive, Suite 232
Cranford, NJ 07016

SUPPLEMENT APPROVAL

Dear Dr. Bishburg:

Please refer to your supplemental new drug application (NDA) dated December 20, 2007, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Inderal (propranolol) 10, 20, 40, 60, and 80 mg Tablets.

This supplemental new drug application provides for the following revisions to the package insert.

1) Addition of the following statement (after the third paragraph) to the **PHARMACOKINETICS AND DRUG METABOLISM/Special Populations/Renal Insufficiency** section of the labeling:

> "Propranolol is not significantly dialyzable."

2) Deletion of the following statement from the **PRECAUTIONS/Drug Interactions** section of the labeling:

> "Disopyramide is a Type I antiarrhythmic drug with potent negative inotropic and chronotropic effects and has been associated with severe bradycardia, asystole and heart failure when administered with propranolol."

3) Deletion of the following statement from the **PRECAUTIONS/Drug Interactions** section of the labeling:

> "Certain ACE inhibitors have been reported to increase bronchial hyper-reactivity when administered with propranolol."

4) Deletion of the following statement from the **PRECAUTIONS/Drug Interactions** section of the labeling:

> "Administration of reserpine with propranolol may also potentiate depression."

5) Modification of the following statement in the **PRECAUTIONS/Drug Interactions** section of the labeling:

From:

"Amiodarone is an antiarrhythmic agent with negative chronotropic properties that may be additive to those seen with propranolol."

To:

"Amiodarone is an antiarrhythmic agent with negative chronotropic properties that may be additive to those seen with β-blockers such as propranolol."

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon electronic labeling text. We will transmit the SPL version of the labeling submitted on December 20, 2007 to the National Library of Medicine for public dissemination.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

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 Dan Brum, Pharm.D., MBA, Regulatory Health Project Manager, at (301)796-0578.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Norman Stockbridge

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