



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-846/S-099

ImaRx Therapeutics, Inc.
Attention: Lynne Weissberger, Ph.D.
Vice President, Regulatory Affairs, Quality Assurance & Regulatory Compliance
1635 E. 18th St.
Tucson, AZ 85719

Dear Dr. Weissberger:

Please refer to your supplemental new drug application dated June 14, 2007, received June 15, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kinlytic™ (Urokinase for injection).

This "Changes Being Effected" supplemental new drug application provides for revisions to the carton and immediate container labeling for Kinlytic™ (Urokinase for injection).

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 14, 2007 (see attached).

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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Diane Leaman, Regulatory Project Manager, at (301) 796-1424.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Acting Director
Division of Medical Imaging and Hematology
Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

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/s/

Rafel Rieves

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