



NDA 21-846/S-101

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

Dear Dr. Weissberger:

Please refer to your supplemental new drug application dated November 20, 2007, received November 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kinlytic™ (urokinase for injection).

We acknowledge receipt of your submissions dated March 25, April 22, and July 3, 2008.

This supplemental new drug application provides for 1) Revision of the **DOSING AND ADMINISTRATION** section of the package insert (PI) to include instructions on using different bags for the loading dose and the maintenance dose of Kinlytic™, 2) Supportive information pertaining to your website, in-service activities, and educational campaign.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and submitted labeling (package insert submitted July 3, 2008) and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-846/S-101.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you of your agreement on July 3, 2008, to revise the website and the promotional, educational and instructional materials in accordance with the revised labeling after final approval of the revised label is received and to submit the revised materials to both the Division and to the division of Drug Marketing, Advertising and Communication. Please inform the Agency when the changes to the Kinlytic web site have taken place.

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  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

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 Mrs. Diane Leaman, Regulatory Project Manager, at (301) 796-1424.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure  
Package Insert

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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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Rafel Rieves

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