



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-846/S-098

ImaRx Therapeutics  
Attention: Lynn E. Weissberger, Ph.D.  
1635 E. 18<sup>th</sup> Street  
Tucson, AZ 85719

Dear Dr. Weissberger:

Please refer to your new drug application (NDA) for Kinlytic (urokinase for injection).

Please refer to your supplemental new drug application dated November 14, 2006, received November 17, 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 15 and May 11, 2007.

This supplemental new drug application provides for revising the product tradename.

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) for the package insert must be identical to the enclosed labeling text for the package insert dated May 11, 2007.

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

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions "SPL for approved NDA 22-138 and NDA 20-164/S-075."

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Alice Kacuba, Regulatory Project Manager Team Leader, at (301) 796-1381.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Rafel Rieves

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