



ADMINISTRATIVE OFFICES
85 ADAMS AVENUE
HAUPPAUGE, NY 11788

631 952 0214 main
631 656 1009 fax

amneal.com

General Correspondence
Transfer of Ownership
ANDA # 074069 (Sequence # 0021)

VIA ELECTRONIC SUBMISSIONS GATEWAY (ESG)

Dr. Kathleen Uhl, Ph.D.
Acting Director
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North VII
7620 Standish Place,
Rockville, MD 20855

January 5, 2015

REF: ANDA # 074069 (Sequence # 0021)

Azathioprine Tablets USP, 50 mg

**General Correspondence - Transfer of Ownership from Roxane
Laboratories, Inc. to Amneal Pharmaceuticals, LLC and Related
Obligations**

Dear Dr. Uhl,

In accordance with CFR Title 21 §314.72(a)(2), Amneal Pharmaceuticals, LLC (Amneal) is notifying the Agency that all rights to the ownership of the above referenced ANDA have been transferred from Roxane Laboratories, Inc. to:

Amneal Pharmaceuticals, LLC
85 Adams Avenue,
Hauppauge, NY 11788

Please note that on **December 30, 2014** Amneal acquired **ANDA # 074069** from Roxane Laboratories, Inc. (See Attached for Roxane's **cover letter** submitted to FDA).

A completed **FDA 356h Form** from Amneal with an original signature is submitted with this submission. This change is effective from January 5, 2015.

Amneal Pharmaceuticals, LLC	Azathioprine Tablets, USP 50 mg
General Correspondence – Transfer of Ownership	ANDA # 074069 (Sequence # 0021)

Also, please note that:

- Amneal commits to the agreements, promises and conditions made by the former application owner, Roxane Laboratories, Inc. as contained in the application.
- Amneal has, in its possession, a full copy of the ANDA, including supplements and records that are required to be kept under 21 CFR 314.81.
- The applications will be maintained by Amneal in accordance with CFR Title 21 § 314.94.
- As of the date of this letter, there are no changes to the application that require reporting under 21 CFR § 314.70. Changes to the label or labeling reflecting a new distributor, will be reported in the next Annual Report.
- All the DMF holders referenced in this application have been informed of the said transfer and it will be ensured that all the DMF updates, if applicable will hereafter be informed to the new ANDA holder

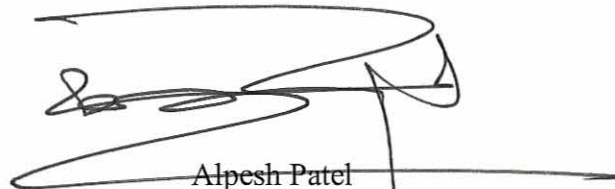
Hereafter, please continue to direct all correspondence pertaining to these applications to:

Alpesh Patel
Vice President, Global Regulatory Affairs
Amneal Pharmaceuticals, LLC
alpesh@amneal.com
Direct: (631) 656 5007
Mobile: (201) 916 2870
Fax: (631) 527 3523

Please do not hesitate to contact the undersigned if you should require any additional information or have any further questions.

Sincerely,

Amneal Pharmaceuticals, LLC



Alpesh Patel
VP, Global Regulatory Affairs
Date: January 5, 2014



Boehringer Ingelheim
Roxane Laboratories

Center for Drug Evaluation and Research
Food and Drug Administration
Office of Generic Drugs
Document Control Room
7620 Standish Place
Rockville, MD 20855

December 30, 2014

Azathioprine Tablets USP, 50 mg
ANDA 074069
Change in Ownership of ANDA

Sarah A. Smith,
Associate Director,
Drug Regulatory Affairs

Telephone: (614) 241-4122
Fax: (614) 276-2470
Email: sarah-a.smith@boehringer-ingelheim.com

1809 Wilson Road
Columbus, Ohio 43228

Dear Sir/Madam:

In accordance with the provisions of 21 CFR §314.72(a)(1), the ownership of the above referenced ANDA has been transferred to the following company:

Amneal Pharmaceuticals, LLC
85 Adams Ave
Hauppauge, New York 11788

Roxane Laboratories, Inc. affirms that all rights to this ANDA has been transferred and a complete copy of the application, including supplements, annual reports, and FDA correspondence has been provided to Amneal Pharmaceuticals, LLC.

Correspondence regarding this notification should be directed to Sarah A. Smith, Associate Director, Drug Regulatory Affairs at (614) 241-4122 or by telefax at (614) 276-2470. In my absence, please contact Debbie Gray, Regulatory Associate, Drug Regulatory Affairs, at (614) 276-4000, extension 2117.

Respectfully,

 For Sarah Smith

Sarah A. Smith.
Associate Director, Drug Regulatory Affairs
Roxane Laboratories, Inc.



NON-REPUDIATION AGREEMENT

VIA FEDERAL EXPRESS

Food and Drug Administration
Office of Regional Operations, Room 3007
12420 Parklawn Drive
Rockville, MD 20857

October 21, 2013

RE: Non-Repudiation Agreement for Digital Signatures

Dear Sir/Madam:

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that Amneal Pharmaceuticals LLC, and its subsidiaries intends that electronic signatures executed by our employees listed in the Attached Table, are the legally binding equivalent of traditional hand-written signatures.

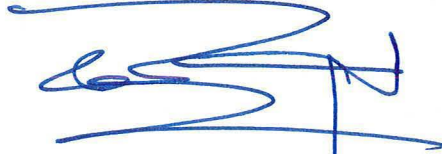
Amneal Pharmaceuticals has the following locations:

- Amneal Pharmaceuticals of NY LLC.
75 Adams Avenue, Hauppauge, NY 11788
50 Horseblock Road, Brookhaven, NY 11719
- Amneal Pharmaceuticals
131 Chamber Brook Road, Branchburg, NJ 08876
209 Mclean Boulevard, Patterson, NJ 07504
1 New England Ave, Piscataway | NJ, 08854
- Amneal Pharmaceuticals, Co. (I) Pvt. Ltd.
882/1-871, Vil. Rajoda, Tal.: Bavla, Ahmedabad-382220, India

- Amneal Life Sciences Private Limited; Parenteral Unit

Plot No. 15, Pharmez SEZ, Sarkhej-Bavla N.H. No. 8A, Vil.: Matoda, Tal.:
Sanand, Ahmedabad-382213, India



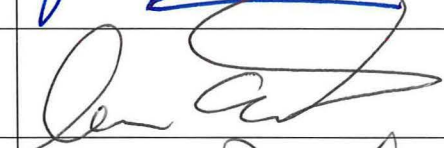
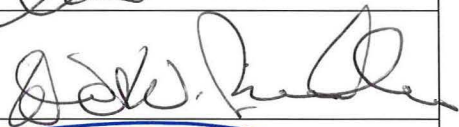
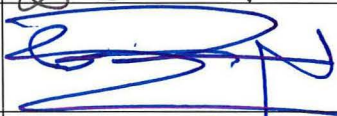
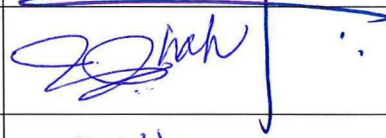

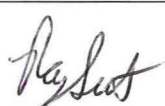



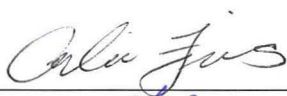
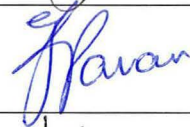

Sincerely,
Amneal Pharmaceuticals









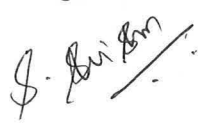





Alpesh Patel
Vice President, Global Regulatory Affairs
Date: October 21, 2013

cc: Attention: Michael B. Fauntleroy
Center for Biologics Evaluation and Research
Office of the Director, HFM - 99, Room 200N
1401 Rockville Pike
Rockville, MD 20852

**Amneal Pharmaceuticals' Employees
Legally Binding Electronic Signatures**

NAME	TITLE	SIGNATURE
Chintu Patel	Chief Executive Officer	
Jiten Parikh	Vice President Operations, Branchburg facility	
Candis Edwards	Senior Vice President Regulatory / Clinical Affairs	
David W. Miller	Senior Vice President Quality Management	
Alpesh Patel	Vice President Global Regulatory Affairs	
Upen Shah	Sr. Director Quality management	
Nigel S. Kiffin	Manager Quality Assurance	
Raj Sutaria	Vice President Quality Assurance	
Robert Chivu	Director Quality Assurance	
Sanjiv Patel	Senior Vice President Operations	
Pamela Fitzpatrick	Director Regulatory Affairs	
Arlin Frias	Associate Director Regulatory Affairs	
Pavan Kumar	Associate Director Regulatory Affairs	
Anil Chapholkar	Senior Manager Regulatory Affairs	

NAME	TITLE	SIGNATURE
Jignesh Modasiya	Senior Manager Regulatory Affairs	
Dr. Nikunj Patel	Executive Vice President Amneal Pharmaceuticals Pvt. Ltd.	
Dr. Priyanka Pawar	General Manager Regulatory Affairs, Amneal Pharmaceuticals Pvt. Ltd.	
Sanjay Kumar Jain	Vice President, Quality Management, Amneal Pharmaceuticals Pvt. Ltd.	
Arpan Patel	General Manager Quality Control, Amneal Pharmaceuticals Pvt. Ltd.	
Jatin Gajjar	Senior Vice President Product Research and Development, Amneal Pharmaceuticals Pvt. Ltd.	
Mr. Naresh Kumar Gaur	Senior General Manager Operations-Manufacturing Amneal Pharmaceuticals Pvt. Ltd.	
Dr. C. A. Rawal	Vice President Operation & Project, Amneal Life Sciences Pvt. Ltd.	
Dr. S. Santhanakrishnan	Director Global Complex Generics and Product Development, Amneal Life Sciences Pvt. Ltd.	
Mr. Anil Chandarana	Sr. General Manager Production, Amneal Life Sciences Pvt. Ltd.	
Dr. Tarun Chugh	Vice President Quality Assurance, Amneal Life Sciences Pvt. Ltd.	
Mr. Prakash C. Jain	Asst. General Manager Quality Assurance, Amneal Life Sciences Pvt. Ltd.	



**ADDENDUM TO ORIGINAL
NON-REPUDIATION AGREEMENT**

VIA FEDERAL EXPRESS

May 16, 2014

Attention: Michael B. Fauntleroy
Food and Drug Administration
Center for Biologics Evaluation and Research
11820 Parklawn Drive, Suite 300
Rockville, MD 20852

RE: Addendum to the Original Non-Repudiation Agreement for Digital Signatures

Dear Sir/Madam:

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that Amneal Pharmaceuticals LLC, and its subsidiaries intends that electronic signatures executed by our employees listed in the Attached Table, are the legally binding equivalent of traditional hand-written signatures.

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Sanand, Ahmedabad-382213, India

Sincerely,
Amneal Pharmaceuticals



Alpesh Patel
Vice President, Global Regulatory Affairs
Date: May 16, 2014

Amneal Pharmaceuticals' Employees
Legally Binding Electronic Signatures

NAME	TITLE	SIGNATURE
Alpesh Chudasama	Manager Regulatory Affairs	
Avnish Patel	Manager Regulatory Affairs	
Surya Medepally	Project Manager Regulatory Affairs	
Shreena Patel	Senior Manager Regulatory Affairs	
Meghana Patel	Senior Manager Regulatory Affairs	
Alpesh Patel	Vice President Global Regulatory Affairs	