AUCTA PHARMACEUTICALS

Improve Delivery Better Medicine

Aucta Pharmaceuticals, LLC.
675 US Route One
North Brunswick, NJ 08902
Tel: 732-640-0030
Fax: 732-640-0030

STATEMENT OF RIGHT OF REFERENCES

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North VII
7620 Standish Place
Rockville, MD 20855

Subject: ANDA#210196, Vigabatrin Powder for Oral Solution, 500 mg/Stickpack

Dear Sir/Madam:

Aucta Pharmaceuticals LLC has obtained the right for references for the DMFs as listed below. Copies of letter of authorization are enclosed.

DMF No.	Material/Component	DMF Holder and Address
027240	Vigabatrin API	MSN Laboratories Private Limited, India
4889	Laminated aluminum foil	Constantia Patz Ges.m.b.H., Austria
16669	Oral dosing syringes	Comar, LLC, New Jersey, USA

Sincerely,

Shoufeng Li, Ph.D.
CEO, Aucta Pharmaceuticals, LLC.
Tel: 732-640-0030, Fax: 732-640-0030

MSN Laboratories Private Limited
MSN House, Plot No.: C - 24,
Sanath Nagar Industrial Estate,
Sanath Nagar, Hyderabad,
Telangana, Pincode: 500 018,
India.
Tel: +91-40-30438600
Fax: +91-40-30438798

LETTER OF AUTHORIZATION

Dated: 20 October 2016
India.

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Central Document Room
Drug Master File Staff
5901-B Ammendale Road
Beltsville, MD 20705-1266
USA

Subject	**Letter of Authorization Issuance for Vigabatrin USP [Route Code – "VB"]**
Type-II DMF #	**027240**
GDUFA PIN for DMF	**GD8005376**

Dear Sir/Madam,

MSN Laboratories Private Limited hereby authorizes **Aucta Pharmaceuticals, LLC** to incorporate by reference information regarding **Vigabatrin USP [Route Code – "VB"]** DMF No. **027240** into any ANDA and its amendments or supplements filed by **Aucta Pharmaceuticals, LLC** for the drug product **Vigabatrin Powder for Solution, 500 mg.** The amendment to DMF No. **027240** was filed on June 29, 2013 as complete eCTD submission with "0000" sequence through FDA Electronic submission gateway.

We also authorize FDA to review all information in the DMF No **027240** when considering any ANDA and its amendments or supplements filed by **Aucta Pharmaceuticals, LLC.** We request that all information in this DMF be treated as confidential to the extent possible in accordance with 21 CFR 314.430 and 21 CFR 20.61, and that no information from this file be provided to any unauthorized persons without our written consent.

The materials furnished will be manufactured in accordance with the DMF and in compliance with good manufacturing practices. MSN Laboratories Private Limited states that the DMF is current and MSN Laboratories Private Limited will comply with the statements made in 21 CFR 314.420. MSN Laboratories Private Limited will notify FDA through an amendment to DMF No **027240** of any addition, change, or deletion of information in the DMF. MSN Laboratories Private Limited will also notify **Aucta Pharmaceuticals, LLC** on the changes that can impact on quality of the subject materials in this letter.

Factory: Sy. No. 317 & 323, Rudraram (Village), Patancheru (Mandal),
Medak District, Telangana, Pincode: 502 329, India.
Tel: +91-8455-305600, Fax: +91-8455-305689, Alternate Fax: +91-40-30438799

MSN Laboratories Private Limited
MSN House, Plot No.: C - 24,
Sanath Nagar Industrial Estate,
Sanath Nagar, Hyderabad,
Telangana, Pincode: 500 018,
India.
Tel: +91-40-30438600
Fax: +91-40-30438798

Dated: 20 October 2016
India.

LETTER OF AUTHORIZATION

API Manufacture:

MSN Laboratories Private Limited,
Sy. No. 317 & 323,
Rudraram (Village),
Patancheru (Mandal),
Medak District,
Telangana,
Pincode: 502 329,
India.
Tel: +91-8455-305600
Fax: +91-8455-305689
Alternate Fax: +91-40-30438799
FEI: 3005254981
DUNS: 863363165
Contact: Mr. S. Somasundaram
E-mail: soma@msnlabs.com

US Agent / Regulatory Agent:
MSN Pharmaceuticals Inc
343 Thornall Street
Suite 678
Edison, NJ 08837, U.S.A
Tel: +1-848-200-1904
+1-848-200-1905
+1-848-200-1906
+1-908-360-1500, Ext: 502/503/504
Fax: +1-678-608-3778
Alternate Fax: +1-732-902-2113
DUNS: 079229051

Contact: Mr. Steven Beagle
Designation: Director
Email: sbeagle@msnlabs.com

MSN Laboratories Private Limited
MSN House, Plot No.: C - 24,
Sanath Nagar Industrial Estate,
Sanath Nagar, Hyderabad,
Telangana, Pincode: 500 018,
India.
Tel: +91-40-30438600
Fax: +91-40-30438798

Dated: 20 October 2016
India.

LETTER OF AUTHORIZATION

ANDA sponsor receiving authorization:

Address: **Aucta Pharmaceuticals, LLC**
675 US Route One,
North Brunswick, NJ 08902

Contact: Shoufeng Li
675 US Route One,
North Brunswick, NJ 08902

Sincerely,
For MSN Laboratories Private Limited

U. Komarelly 20/10/16

U. Komarelly,
AGM- Regulatory Affairs
komarelly.u@msnlabs.com
Fax: +91-8452-304701

KILPATRICK TOWNSEND
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Noelle E. Wooten
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direct fax 704 371 8323
NWooten@KilpatrickTownsend.com

August 18, 2016

VIA OVERNIGHT MAIL

Drug Master File Staff
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

Re: Letter of Authorization to incorporate by reference sections of DMF No. 4889, Type III (Aluminum foil packaging materials for drug products), relating to confidential formation referred to as PATZ 47436

Aucta Pharmaceuticals LLC

Dear FDA Reviewer:

We submitted a letter on behalf of our client and corporate holder, **Constantia Patz Ges.m.b.H. ("Constantia Patz")**. By copy of this letter, **Constantia Patz** authorizes **Aucta Pharmaceuticals LLC** to incorporate by reference specific pages in Constantia Patz's Drug Master File (DMF) No. 4889, for any New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or Investigational New Drug Application (INDA) filed by **Aucta Pharmaceuticals LLC** with the Food and Drug Administration (FDA). **This Letter of Authorization (LOA) is specific to the portions of DMF No. 4889, relating to PATZ 47436,** which was incorporated into DMF No. 4889, on October 3, 2014, and is described in Section D of DMF No. 4889, on pages D.53.1-.5 (Confidential Formulations), with supporting raw material specifications documentation in Section F of DMF No. 4889.

Constantia Patz authorizes the Food and Drug Administration to review Drug Master File No. 4889, in furtherance of this letter of authorization. The information in DMF No. 4889 is intended to assist FDA in its review of applications filed with respect to new drugs in accordance with 21 C.F.R. Section 314.420. It is our understanding that the information included in the DMF, and any information that may be added subsequently, will be afforded appropriate confidential treatment in accordance with the provisions of Section 314.430, dealing with the confidentiality of data in NDAs and ANDAs, and FDA's Public Information Regulations set forth at 21 C.F.R. Part 20.

Lastly, if possible, **we would appreciate you acknowledging receipt of this letter of authorization by file stamping and returning the enclosed copy of this letter in the enclosed self-addressed stamped envelope.**

Thank you in advance for your assistance. As always, if you have any questions regarding this letter of authorization or the above product, please feel free to contact me at (704) 338-5010.

With best regards.

Very truly yours,

Noelle E. Wooten
Legal Agent for Constantia Patz Ges.m.b.H.

Enclosures
NEW/nw

cc: Mr. Shoufeng Li (via Dr. Katharina Gallas)
Aucta Pharmaceuticals LLC
675 US Route One
North Brunswick, NJ 08902
Tele: 732. 640.0030
Cell: 908.432.6426
Cell: 139.1874.1306 (China)
E-mail: shoufeng.li@auctapharma.com

Stefan Frischmann (via electronic mail only)
Head of Product Development
Pharma/Healthcare
Constantia Hueck Folien GmbH & Co. KG
P.O. Box 1758
D-92607 Weiden
Germany
E-mail: StefanFrischmann@constantia-hueck.com

Dr. Katharina Gallas (via electronic mail only)
Regulatory Affairs Manager and Technical Identity
Constantia Patz Ges.m.b.H.
Guntramserstrasse 7
A-2620 Loipersbach
Austria
E-mail: katharinagallas@patz.cflex.com

SciRegs International, Inc.
PHARMACEUTICAL SCIENCES AND REGULATORY AFFAIRS

SciRegs International, Inc.
6333 Summercrest Drive
Columbia MD 21045 USA

1.4.1 Letters of Authorization

Drug Master File Staff
Central Document Room
Food and Drug Administration
5901-B Ammendale Rd.
Beltsville, MD 20705-1266

December 8, 2016

Re: DMF 16669 Type III for Dosage Delivery Systems
Held by: COMAR, LLC.
Originally Filed: June 6, 2003

Dear Sir or Madam:

SciRegs International, Inc., US Regulatory Agent for COMAR, LLC., hereby grants permission to the FDA to access the DMF on behalf of Aucta Pharmaceuticals, in order to incorporate by reference information relating to the referenced Oral Dosing Assembly provided in the Type III DMF 16669, COMAR part numbers 41-0001-057 and 41-0005-060 into any IND, NDA, ANDA, supplement or US CTD filed by:

Aucta Pharmaceuticals
675 U.S. Highway 1
North Brunswick, NJ 08902

Information regarding COMAR materials of construction used in part numbers 41-0001-057 and 41-0005-060 is provided in the table below.

Parent Item: 41-0005-060 – 10 mL Oral Dispenser Assembly (Short Tip)	
22-0526-001 10 mL Plunger, white	13-0048-001 Resin, Exxon Mobil 6908.19 HDPE
	15-0008-001 Colorant, Teknor White 93,947 CP
22-0544-001 Plain Barrel, 10 mL Short Tipped	13-0013-001 Resin, Exxon Mobil Clarified 9074 PP
	15-0180-001 Additive, Ampacet 103177 Slip PP MB
18-0759-001	Ink, Dense Black 7707 Zeller Gmelin
28-1164-001	Wrap, PE Preformx C559T-X014006, 4.5 87” gauge

Parent Item: 41-0001-057 – 3 mL Oral Dispenser Assembly (Short Tip)	
22-0107-001 3 mL Plunger	13-0048-001 Resin, Exxon Mobil 6908.19 HDPE
	15-0008-001 Colorant, Teknor White 93,947 CP
22-0462-001 Plain Barrel, 3 mL Short Tipped	13-0013-001 Resin, Exxon Mobil Clarified 9074 PP
	15-0180-001 Additive, Ampacet 103177 Slip PP MB
18-0759-001	Ink, Dense Black 7707 Zeller Gmelin
28-1160-001	Wrap, PE Preformx C559T-X014006, 3.25 87" gauge

We request that all information in this file be treated as confidential to the extent possible in accordance with 21 CFR § 314.430 and 21 CFR § 20.61, and that no information from this file be provided to any unauthorized persons without our written consent.

The materials furnished will be manufactured in accordance with the DMF and in compliance with applicable good manufacturing practices. COMAR states that this DMF is current and COMAR will comply with the statements made within it. Notification to Aucta Pharmaceuticals and an appropriate notification to FDA will be made for changes that impact the subject materials of this letter.

Under the FD&C Act, Section 303(c) (2), COMAR hereby guarantees that

- It will retain records of the receipt, testing, and supplier information, and make available such records to the FDA, upon request.
- It is acting in good faith and that to the best of its knowledge; the materials used in the fabrication of above listed articles are not adulterated or misbranded.

Please be advised that it is ultimately the responsibility of the end user to determine the acceptability of use of this component with their product.

This completes our submission. The DMF has been prepared in compliance with the eCTD format and is provided in text-based pdf formatting. SciRegs certifies that the submission is virus free and was created in eCTD using MedXView eComposer Version 3.2. A copy of our Letter of Appointment is on file in the DMF. Please feel free to contact Brian James Reamer if you have further questions, at SciRegs International, Inc., US Regulatory Agent for COMAR LLC., at Phone 410-309-3145; FAX 410-309-6145 or email Brian.Reamer@SciRegs.com.

Sincerely yours,

Brian James Reamer
VP of Quality Assurance
SciRegs International, Inc.
US Regulatory Agent for COMAR LLC.

Cc:
Jason Tao, Aucta Pharmaceuticals
Russ Granato, Comar LLC.

One Comar Place
Buena, NJ 08310

APPOINTMENT OF U.S. REGULATORY AGENT

To Whom It May Concern:

Comar LLC., hereby appoints Brian James Reamer and SciRegs International Inc. as U.S. Regulatory Affairs Agent for Comar LLC, in the filing of information with the U.S. Food and Drug Administration. The corporate contact information for both Comar LLC. and SciRegs International Inc. is listed below.

Comar LLC.
Russ Granato
One Comar Place
Buena, NJ 08310
Phone (856) 507-5468
FAX (856) 794-9721

SciRegs International Inc.
Brian James Reamer
6333 Summercrest Drive
Columbia, MD 20145
Phone: (410) 309-3145
Facsimile: (410) 309-6145

Sincerely yours,

Russ Granato
Comar LLC.
One Comar Place
Buena, NJ 08310

Date 01/02/2014