Deepika Reddy

From: Deepika Reddy
Sent: 15 September 2020 17:28
To: Yakara David Levinson
Subject: FW: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804
Attachments: FDA records receipt confirmation, Glochem Industries, FEI: 3005818804

From: Vamsi Vodnala <vamshi.vodnala@glochemindia.com>
Sent: 15 September 2020 17:19
To: Deepika Reddy <deepika.reddy@glochemindia.com>
Subject: FW: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

From: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Sent: 26 August 2020 23:18
To: Vamsi Vodnala <vamshi.vodnala@glochemindia.com>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: FW: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Vamshi Vodnala,

Thank you for your message. Please find the attached which was emailed to Subbarao Kattamuri on 06/30/20 and is the confirmation that the records have been confirmed and the review is closed.

Best regards,

Pharmaceutical Quality Initiatives Branch
Division of Pharmaceutical Quality Programs

Office of Pharmaceutical Quality Operations
Office of Regulatory Affairs
U.S. Food and Drug Administration

From: Vamsi Vodnala <vamshi.vodnala@glochemindia.com>
Sent: Tuesday, August 25, 2020 4:41 AM
To: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Steven E. Porter,

Hope you are doing well.

I would like to request you to confirm on the status of review of information provided against the FDA Pre-Inspection Records Request.

Many thanks in advance.

Thanks & Regards,

Vamshi Vodnala
Asst. General Manager - Regulatory Affairs
Glochem Industries Limited
+91-7331106568

From: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Sent: 23 June 2020 20:43
To: Vamsi Vodnala <vamshi.vodnala@glochemindia.com>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Vamsi Vodnala,
Thank you for your message. The records are currently being reviewed. At this time, there are no questions. You will receive an official confirmation when it has been completed.

Thank you,

Pharmaceutical Quality Initiatives Branch
Division of Pharmaceutical Quality Programs
Office of Pharmaceutical Quality Operations
Office of Regulatory Affairs
U.S. Food and Drug Administration

From: Vamsi Vodnala <vamshi.vodnala@glochemindia.com>
Sent: Tuesday, June 23, 2020 6:08 AM
To: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Steven E. Porter,

We suppose the information provided against the FDA Pre-Inspection Records Request is adequate. Please let us know if you find any of your expectations are not met in our submission and we will comply with requirements.

Thanks & Regards,

Vamshi Vodnala
Manager - Regulatory Affairs
Glochem Industries Limited
+91-7331106568

From: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Sent: 28 May 2020 21:36
To: Vamsi Vodnala <vamshi.vodnala@glochemindia.com>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Vamshi Vodnala,
Thank you for your message. The emails were received and are currently being reviewed. You will receive an official confirmation when the records have all been reconciled.

Thank you,

Pharmaceutical Quality Initiatives Branch
Division of Pharmaceutical Quality Programs
Office of Pharmaceutical Quality Operations
Office of Regulatory Affairs
U.S. Food and Drug Administration

From: Vamsi Vodnala <vamshi.vodnala@glochemindia.com>
Sent: Thursday, May 28, 2020 2:59 AM
To: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Steven E. Porter,

I am writing this email in reference to Pre-Inspection Records submitted on 16th of May, 2020.

I request you to kindly acknowledge the well receipt of the all 5 sequential mails consisting Pre-Inspection Records.

Thanks & Regards,

Vamshi Vodnala
Manager - Regulatory Affairs
Glochem Industries Limited
+91-7331106568

From: Vamsi Vodnala
Sent: 16 May 2020 18:31
To: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Steven E. Porter,

This is Mail No.4, last of sequential mails and this mail contains the below attachments,

1. Annexure_3.1b US Dispatch data.XLSX
2. Annexure_5.1 Material Management Procedure.pdf
3. Annexure_5.3 Schematics of Material Staging Areas.pdf
4. Annexure_5.4 Batch Coding Explanation.pdf
5. Annexure_5.5 Material Qualification.xlsx
6. Annexure_6.1 List of Retest Samples.pdf
7. Annexure_6.2 List of Stability Studies.zip
8. Annexure_6.4 Elemental Impurities Risk Assessment.zip
9. Annexure_6.5 All Release Specifications and Results.zip
10. Annexure_7.1 Packing Configuration.pdf
11. Annexure_7.2 Copy of Labels.pdf

Please acknowledge the receipt of all the 5 mails, including the first mail containing the duly filled FDA Pre-Inspection Records Request and all 37 attachments.

Thanks & Regards,

Vamshi Vodnala
Manager - Regulatory Affairs
Glochem Industries Limited

+91-7331106568

From: Vamsi Vodnala
Sent: 16 May 2020 17:43
To: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Steven E. Porter,

This is Mail No.3 of sequential mails and this mail contains the below attachments,

1. Annexure_4.1 Site Layout.pdf
2. Annexure_4.2 Area Layouts.zip
3. Annexure_4.3 Utilities.zip
4. Annexure 4.4 Process Flows.zip
5. Annexure_4.5 Cleaning Procedure.pdf
6. Annexure_4.6 Cleaning Validation.pdf
7. Annexure_4.7 List of Manufacturing Equipment.pdf
8. Annexure_4.8 Summary of Equipment Qualification.pdf
9. Annexure_4.9 Calibration .xlsx

Thanks & Regards,

Vamshi Vodnala
Manager - Regulatory Affairs
Glochem Industries Limited
+91-7331106568

From: Vamsi Vodnala
Sent: 16 May 2020 17:28

To: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Steven E. Porter,

This is Mail No.2 of sequential mails and this mail contains the below attachments,

1. Annexure_2.1 Summary list of Investigations.xlsx
2. Annexure_2.2 Summary list of Customer Complaints.xlsx
3. Annexure_2.4 Annual Trends of Environmental Monitoring.zip
4. Annexure_2.6 Tools for Investigation.zip
5. Annexure_3.1b US Dispatch data.XLSX
6. Annexure_3.2 List of batches released, rejected & returned.zip
7. Annexure_3.3 List of Manufacturing Process Changes.zip
8. Annexure_3.5 Explanation of Lot Numbering System.pdf

Thanks & Regards,

Vamshi Vodnala
Manager - Regulatory Affairs
Glochem Industries Limited
+91-7331106568

From: Vamsi Vodnala
Sent: 16 May 2020 17:23
To: 'ORA PHARM FDASIA 706 Requests' <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Steven E. Porter,

This is Mail No.1 of sequential mails and this mail contains the below attachments,

1. Annexure_1.1 Site Master File.pdf
2. Annexure_1.2 Organisation chart.pptx
3. Annexure_1.7 Operating Hours.pdf
4. Annexure_1.8 Description of Establishment.zip
5. Annexure_1.10 Out Sourced Services.pdf
6. Annexure_1.12 Major Changes.zip
7. Annexure_1.13 Training.zip
8. Annexure_1.14 Regulatory Inspection Outcome.zip
9. Annexure_1.15 Regulatory Activities.pdf

Thanks & Regards,

Vamshi Vodnala
Manager - Regulatory Affairs
Glochem Industries Limited
+91-7331106568

From: Vamsi Vodnala
Sent: 16 May 2020 17:19
To: 'ORA PHARM FDASIA 706 Requests' <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Steven E. Porter,

Greeting for the day.

Please find the duly filled FDA Pre-Inspection Records Request attached. All supporting annexure (37) are being shared with you in subsequent emails due to restriction on the size of the attachments.

Please let us know if you find any of the required information is missing and we will comply with requirements.

Thanks & Regards,

Vamshi Vodnala
Manager - Regulatory Affairs
Glochem Industries Limited
+91-7331106568

From: Vamsi Vodnala
Sent: 02 May 2020 10:51
To: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Cc: Subbarao Kattamuri <md@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Steven E. Porter,

We acknowledge the receipt of the email and have made note of correction in email ID in form 4003. As advised by you, all the future communications will be made to ORAPHARMFDASIA706REQUESTS@fda.hhs.gov.

Thanks & Regards,

Vamshi Vodnala
Manager - Regulatory Affairs
Glochem Industries Limited
+91-7331106568

From: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Sent: 01 May 2020 23:47
To: Vamsi Vodnala <vamshi.vodnala@glochemindia.com>
Cc: Subbarao Kattamuri <md@glochemindia.com>; Sandeep Kattamuri <sandeep.kattamuri@glochemindia.com>
Subject: [WARNING: MESSAGE ENCRYPTED]RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Vamsi Vodnala,
An updated 4003 is attached with corrected email contact. Please use ORAPHARMFDASIA706REQUESTS@fda.hhs.gov .

Thank you

Pharmaceutical Quality Initiatives Branch
Division of Pharmaceutical Quality Programs
Office of Pharmaceutical Quality Operations
Office of Regulatory Affairs
U.S. Food and Drug Administration

From: ORA PHARM FDASIA 706 Requests
Sent: Tuesday, April 21, 2020 8:50 AM
To: Vamsi Vodnala <vamshi.vodnala@glochemindia.com>; ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Cc: Subbarao Kattamuri <md@glochemindia.com>; Sandeep Kattamuri <sandeep.kattamuri@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Vamsi Vodnala,
Thank you for your message and the acknowledgement. In response to your question, I have been informed that there is a 100MB email file size limit. However, please be advised that larger file sizes may take longer to process by the FDA network.

Thank you.
Joey Quitania, Investigator/CSO

Pharmaceutical Quality Initiatives Branch
Division of Pharmaceutical Quality Programs
Office of Pharmaceutical Quality Operations
Office of Regulatory Affairs
U.S. Food and Drug Administration

From: Vamsi Vodnala <vamshi.vodnala@glochemindia.com>
Sent: Sunday, April 19, 2020 11:18 PM

To: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Cc: Subbarao Kattamuri <md@glochemindia.com>; Sandeep Kattamuri <sandeep.kattamuri@glochemindia.com>
Subject: RE: FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

Dear Sir/ Madam,

I am Vamshi Vodnala taking care of Regulatory at Glochem.

Hereby, we acknowledge the receipt of FDA Pre-Inspection Records Request and would like to confirm our acceptance to submit all the information requested in FDA Pre-Inspection Records Request to the notice on or before the stipulated date 16th May 2020.

Considering that weblinks cannot be used to share the requested data and all the data needs to be sent through email, I would like to request you to advise on the maximum size of the incoming email.

Thanks & Regards,

Vamshi Vodnala
Manager - Regulatory Affairs
Glochem Industries Limited
+91-7331106568

From: ORA PHARM FDASIA 706 Requests <ORAPHARMFDASIA706REQUESTS@fda.hhs.gov>
Sent: Friday, April 17, 2020 4:36:49 AM
To: Subbarao Kattamuri <md@glochemindia.com>
Subject: [WARNING: MESSAGE ENCRYPTED]FDA request for records: Glochem Industries Limited (India) - FEI 3005818804

To: Subbarao Kattamuri, Managing Director

Under section 704(a)(4) of the Federal Food, Drug and Cosmetic Act (FD&C Act) [21 USC 374(a)(4), FDA requests that you provide the records described in the attached FDA Form 4003. If the records requested do not exist, please state that fact in your response.

Though the form is titled "FDA Pre-Inspection Records Request", per 374(a)(4), these records may be used in advance of or in lieu of inspection.

For more information, please see the FDA Staff Manual Guide 9004.1: Policy and Procedures for Requesting Records in Advance of or In Lieu of a Drug Inspection.

Please reply to this email acknowledging receipt of the request for records.

Pharmaceutical Quality Initiatives Branch
Division of Pharmaceutical Quality Programs
Office of Pharmaceutical Quality Operations
Office of Regulatory Affairs
U.S. Food and Drug Administration

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FDA Inspection Records Receipt Confirmation

Requesting Office Street Address	City	State	Zip Code
19701 Fairchild	Irvine	CA	92612
To: Name of Individual	**Title of Individual**		**Date of Request**
Subbarao Kattamuri	Managing Director		04/16/2020
Firm Name			
Glochem Industries Limited			
Firm Street Address	**City**	**State**	**Zip Code**
174 to 176 Survey Nos	Hyderabad, Telangana		
Country			
India			

This constitutes a confirmation of receipt of records requested under the Federal Food, Drug, and Cosmetic Act section 704(a)(4) [21 U.S.C. 371(a)(4)]. This confirmation affirms only that FDA has received the records submitted. It does not imply that the records submitted are complete, responsive, or otherwise satisfy the request.

DESCRIPTION OF RECORDS REQUESTED

See attached list

The above-described records were received on (date) 05/16/2020

FDA Contact Email	FDA Contact Phone Number
ORAPHARMFDASIA706REQUESTS@fda.hhs.gov	
Typed Name and Title of FDA Contact	**Signature of FDA Contact**
CDR Steven E. Porter, Jr., Director DPQO IV	Steven E. Porter Jr -S Digitally signed by Steven E. Porter Jr -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300433092, cn=Steven E. Porter Jr -S Date: 2020.06.25 09:29:15 -07'00'