

From: [Dr Juma Venkatesh](#)
To: [CDER-OC-OMQ-Communications](#)
Cc: venkatesh@global-pharma.com; [Wackes, Frank](#)
Subject: Re: [EXTERNAL] U.S. FDA Official Correspondence to Global Pharma Healthcare Private Limited - FEI 3012323885
Date: Tuesday, January 10, 2023 1:55:35 PM
Attachments: [US FOOD & DRUG LETTER.pdf](#)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

TO:
MR Milind Ganjawala (Director)
MR Frank Wackers (Consumer Safety officer)
Division of Drug Quality 11
Office of Manufacturing Quality
Center for Drug Evaluation and Research

Ref : FEI 3012323885

sirs,

Good day , We have communicated our response to your email dated january. 5 th 2023. We would like know if additional clarifications are required from our organization to further explain our understanding of filing form 4003.

We would like to an appointment by telecon or. zoom or team to enable us to understand the next course of action that we need to conduct to establish our continuous efforts to follow the USFDA guidelines. for our products.

We sincerely would await your response. for the trailing email with attachments.

looking forward to your positive response.

Best Regards

Dr .Venkatesh
CEO
Global Pharma Healthcare pvt ltd.

On Fri, Jan 6, 2023 at 12:44 AM CDER-OC-OMQ-Communications <CDER-OC-OMQ-Communications@fda.hhs.gov> wrote:

Hello,

This confirms receipt of your email submission with an attachment.

Thank you,

CDER-OC-OMQ-Communications

From: Dr Juma Venkatesh <prarthanaraj@gmail.com>

Sent: Thursday, January 5, 2023 10:08 AM

To: CDER-OC-OMQ-Communications <CDER-OC-OMQ-Communications@fda.hhs.gov>; Wackes, Frank <Frank.Wackes@fda.hhs.gov>; venkatesh@global-pharma.com

Subject: [EXTERNAL] U.S. FDA Official Correspondence to Global Pharma Healthcare Private Limited - FEI 3012323885

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TO:

MR Milind Ganjawala (Director)

MR Frank Wackers (Consumer Safety officer)

Division of Drug Quality 11
Office of Manufacturing Quality
Center for Drug Evaluation and Research

Dear Sir,

We confirm receipt of your email dated jan 5, 2023.

We have given our detailed explanation mentioning our compliance to 21 CFR 211.160(b) and 21 211.84(d) (2).

We would appreciate your review of our letters and response.

We are hoping that you would factually consider our request for removal from import alert.

Best regards

Dr. Venkatesh A.R.

CEO

www.global-pharma.com

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Best Regards,
Dr Juma Venkatesh
CEO
Global Maharaja Pte Ltd
Mobile:+959420071126/+917358405541
Whatsapp/Viber No: 00959420071126