U.S. FOOD & DRUG ADMINISTRATION

Date: December 3, 2022

To: Dr Juma Venkatesh

FEI: 3012323885

DUNS: 860186917
Firm Name and Address:
Global Pharma Healthcare Pvt LTD
A-9, SIDCO Pharmaceutical Complex
Chennai Tamil Nadu 603110 India

E-mail: prarthanaraj@gmail.com
Phone: 91-735-840-5541

From:
Office of Quality Surveillance
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
US Food and Drug Administration

E-mail:
PharmaRecordsRequest@fda.hhs.gov

This is an official notification that the United States Food and Drug Administration (USFDA) has requested information from your establishment via the Establishment Contact email address provided in your current USFDA drug registration in the Electronic Drug Registration and Listing System on the following dates:

November 15, 2022, November 23, 2022, and call on December 2, 2022

USFDA has NO RESPONSE to these requests from your establishment to date.

Under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)(4)], FDA requests that you provide the records described below. If the records requested do not exist, please state that fact in your response.

The requests were sent from PharmaRecordsRequest@fda.hhs.gov as indicated by the enclosed copies of messages along with the original request and the FDA Form 4003 attachment.

You should respond to the aforementioned request and reminder via email by **December 16, 2022**. Your response should be recorded in the attachment and emailed to PharmaRecordsRequest@fda.hhs.gov.

You may also email PharmaRecordsRequest@fda.hhs.gov to request the attachment if you no longer have it in your email system.

Failure to submit the requested records by the date requested may cause your product to be adulterated within the meaning of section 501(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 351(j)]. Failure to respond to a section 704(a)(4) records request may result in all drugs manufactured by your firm to be subject to refusal of admission.