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To,

Nov 7th,2023

U.S Food and Drug Administration,

12420 Parklawn Drive, Room 2032

Rockville ,MD 20857

Reference:Warning letter number 320-24-03

Fei No:3012323885

Subject : Response to warning letter dated October 20 th,2023

We are writing to formally acknowledge the receipt of Warning Letter Number 320-24-03, which we received via email.

With regard to the CGMP violations cited, we have taken note of your concerns regarding our response to the issues raised in the Form 483. We have a consultant in our team to assist with the review and improvement of our facility ,however we are currently in the process of shortlisting a significantly more qualified consultant who can assist us in effecting the necessary remediations to ensure compliance with CGMP standards. The chosen consultant will also conduct a comprehensive six-system audit of our entire operation, evaluating the completion and efficacy of all corrective actions taken.

a) We take our responsibility to address and rectify all deficiencies noted by the FDA inspectors with the utmost seriousness. In light of our commitment to resolve these issues comprehensively, we kindly request an extension of time until February 2024 to secure a consultant who meets the required qualifications, we will update with firm timelines once we have a qualified consultant in place.

In the interim, we would like to reiterate the following actions we have taken:

b) We have promptly withdrawn our registrations and canceled all listings at USAFDA
c) We have proactively suspended production in our sterile section and no longer manufacture any products in this section, as previously communicated.
d) We have no intentions of resuming manufacturing in the sterile section until all deficiencies have been effectively resolved. We assure our commitment to not circumvent the process.

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e) With regards to the concern about our listed drug products containing EG/DEG,we would like to reiterate that we have not manufactured any of the products listed in the drug listing for USA',also we have cancelled all the drug listings and we have no active drug listing in USA FDA..None of the products listed have been exported to USA .We will provide a very detailed response to the query on EG/DEG within the stipulated time .

f) We assure our commitment to provide a more adequate response to points where you have qualified our response as inadequate .

g) We hope a qualified consultant will assist in our remediation process and we will be able to meet adequately the requirements raised by your good office.

Should you require any additional information or updates during this interim period, please do not hesitate to contact us.

Sincerely,

Dr A.R Venkatesh

Chief Executive Officer
Global Pharma Healthcare Pvt Ltd

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