Global Pharma Healthcare Pvt. Ltd.,
A-9, SIDCO Pharmaceutical Complex, Alathur, Thiruporur - 603 110.
Kanchipuram District, Tamilnadu, INDIA.
+91-44-2744 4408 venkatesh@global-pharma.com
www.global-pharma.com

Dated: 5th January 2023

To
Mr.Milnd Ganjawala (Director) / Mr . Frank Wackes (Consumer Safety Officer)
Division of Drug Quality II
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

Dear Sir

We have manufactured and exported to US the following products to DELSAM PHARMA LLC , BRONOX – NEWYORK – 10647

1. **Artificial Tears Lubricant Eye Drops**
   Active ingredient:
   Carboxymethylcellulose Sodium
   Inactive ingredient:
   (b) (4)
   Both active & inactive ingredients are not contains high risk components which contains di ethylene glycol & ethylene glycol

2. **Artificial Eye ointment**
   Active Ingredient:
   Minerial oil 15 %
   White Petroleum 83 %
   And No inactive ingredients
   Both active substance is not contains high risk components which contains di ethylene glycol & ethylene glycol

GLOBAL PHARMA HEALTHCARE PVT. LTD. India

Admin Office: No. 2A, 3rd Fl, 4th Street, Ganga Nagar, Kodambakkam, Chennai - 600 024. INDIA.
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Hence we have mentioned in Serial Number 1 column (do you manufacture finished drug products or components (e.g, ingredients , processing aids) containing high – risk components such as propylene glycol, glycerine , polyethylene glycol , sorbitol solution , maltitol solution , and / or hydrogenated starch hydrolysate ?) as **" NO "**

We have registered certain products in OTC monograph for the year 2021, registration has not been extended for 2022 and not made any export till date to USA directly or Indirectly

We have IN – HOUSE quality control LAB with ISO 17025 certificate, Our lab complies (21 CFR 211.160(b)) and (21 211.84 (d) (2)) , has been audited and approved by various Ministry of Health

- Food , Medicine abd Healthcare , Administration and Control Authority of Ethiopia
- Pharmacy and Poisons Board of Kenya
- Direction de la Pharmacie du Medicament et des Laboratories de Cote divore (Ivory Coast)
- The Food and Drugs Board of Ghana
- Pharmacy Medicines & Poisons Board of Malawi
- Medicines & Health products regulatory Authority – Liberia
- Pharmacy Board of Sierraleone
- Ministry of Health Cambodia
- The Ministry of Health DR Congo
- National Agency for Food and Drug Administration and Control – NAFDAC
- Ministry of Health , Social Security and National Solidarity , Gabon
- Ministry of Health , Yemen
- Ministry of Public Health , Cameroon
- Department of Health Food and Drug Administration – Republic of the Philippines

And we are also audited by SGS and Mission Pharma , Denmark and supplying medicine to UNOPS

Our site is going to have EU audit during 3rd week of January 2023

Hence we request you to consider to remove us from import Alert 66-40

If we manufacture formulation which contains high – risk components contains di ethylene glycol & ethylene glycol, we will fill FDA form 4003 and we will do process validation, Analytical method validation and share COA and all other supporting documents.

Sincerely

For Global Pharma Healthcare Pvt Ltd

K. Selvam
(General Manger – Quality Assurance)

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