Fera Pharmaceuticals, LLC
134 Birch Hill Road
Locust Valley, New York 11560

July 31, 2023

**IMPORTANT DRUG INFORMATION**

**Subject: Shelf-Life Extension for Phospholine Iodide® 0.125%, for ophthalmic solution, 6.25 mg/5 mL vial**

Dear Healthcare Provider,

To prevent a supply disruption, the U.S. Food and Drug Administration (FDA) approved a shelf-life extension for Phospholine Iodide (echothiophate iodide for ophthalmic solution), 0.125%, from 36 months to 48 months based on available stability data, when stored according to labeled storage and handling requirements:

| Product Description | NDC | Lot/ Batch # | Expiration Date (Labeled) | Extended Expiration Date |
|---|---|---|---|---|
| Phospholine Iodide Lyophilized 6.25 mg/5 mL vial | 48102-053-05 | 1850-140A | 05/2023 | 05/2024 |

You may have already received Phospholine Iodide labeled with the 36-month expiration date of May 2023. **Please do not discard this Phospholine Iodide as it can continue to be used for additional 12 months until May 2024.**

The FDA is not requiring or recommending that the Phospholine Iodide remaining from the above lot be relabeled with the new expiration date. Pharmacist, please include the use-by date on the product and dispense the Dear Patient letter with each prescription. FERA is the sole supplier of Phospholine Iodide in the US. Phospholine Iodide is indicated for treatment of increased intraocular pressure and accommodative esotropia.

For additional questions about the information contained in this letter, please contact FERA at (516) 277-1449 or visit the FDA website at www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages.

Healthcare providers and patients are encouraged to report adverse events in patients using Phospholine Iodide to FERA at 1-414-434-6604.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm

- **Regular mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

We appreciate your immediate attention to this matter.

Sincerely,

Michelle Kim, PharmD.
Sr. Director, Regulatory Affairs