

May 31, 2022

Notification Regarding Potential Defect for Phospholine Iodide® for Ophthalmic Solution

Dear Customer and Healthcare Provider,

FERA Pharmaceuticals, LLC (“FERA”) is the sole supplier of the product Phospholine Iodide in the USA, indicated for treatment of increased intraocular pressure and accommodative esotropia. FERA has identified a potential defect in seal/crimp for the most current manufactured batch of Phospholine Iodide (batch # 1850-140A):

Product Description	Fera NDC	Batch Number	Expiry Date
Phospholine Iodide (echothiophate iodide)	48102-053-05	1850-140A	May 2023

Most defects detected are minor cosmetic defects, including a missing aluminum disc, and nicks, dents, or scratches on the green seals on the lyophilized product vial. Visually inspect the vial for integrity of the seal. Do not use if the seal is not intact.

In the event that vials present with mangled, angled or detached green seals, **FERA will provide replacements for any product deemed undesirable by pharmacists and healthcare providers.** For additional questions about the information contained in this letter, please contact FERA at (516) 277-1449.

In addition, the packaging of this product does not include serialization information and does not meet the product identifier requirements of section 582(b)(2) of the Federal Food, Drug and Cosmetic Act*.

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).

This letter is not intended to be a complete description of the benefits and risks related to the use of Phospholine Iodide. Please refer to the enclosed full prescribing information.

We appreciate your immediate attention to this matter.

*This exemption was conducted with the knowledge of the U.S. Food and Drug Administration



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

Sincerely,

A handwritten signature in black ink, appearing to read "Michelle Kim". The signature is fluid and cursive, with the first name "Michelle" and last name "Kim" clearly distinguishable.

Michelle Kim, PharmD.
Sr. Director of Regulatory Affairs