Liebel Flarsheim Company LLC
8800 Durant Rd.
Raleigh, NC 27616

31July26

URGENT DRUG RECALL – Injectable

Dear Loyal Customer,

This is to inform you of a voluntary product recall involving:

OPTIRAY® Imaging Bulk Package (IBP)- 350, 500mL, VIAL, Lot 25ZF3670, NDC 0019-1333-65, expiration date May 31, 2027

(Ioversol Injection 74%, 350mg/mL Organically Bound Iodine).

Please see the enclosed product label for ease in identifying the product at the user level (hospitals, imaging centers, healthcare facilities and clinics, and other potential users of the product).

This voluntary recall has been initiated due to the presence of particulate matter. If product containing particulate matter is administered intravenously, it may pose a risk to patient safety including local irritation or swelling of the vein in response to the foreign material. More serious potential risks following intravenous or intra-arterial injection of solid particles could include focal blockage of blood vessels (e.g., in the lungs), focal thrombotic events and/or microinfarction in downstream tissues. To date, no adverse events or injuries associated with this lot have been reported.

We began shipping this lot on October 22, 2025, and concluded shipment on January 12, 2026.

Actions:

1. Immediately examine your inventory and quarantine product subject to recall. Immediately stop distribution and use of the recalled product.

2. Complete the attached acknowledgement form, even if you do not have any of the identified product remaining in stock, and return the form within 2 business days to the below email address or fax number. Returning this form is important to the recall and reconciliation process.

Rxrecalls@inmar.com or **Fax: 817-868-5362**

3. Upon receipt of the completed acknowledgement form, Inmar will issue the corresponding shipping label and arrange pick-up of the affected stock to be returned to FedEx.

Returned stock will be credited to your account. Replacement stock can be ordered through Guerbet Customer Service.

4. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. **This recall should be carried out to the user level (hospitals, imaging centers, healthcare facilities and clinics, and other potential users of the product).** When notifying your customers, you should provide a copy of this recall notification letter.

For further information please contact

Inmar Rx Solutions

By email: rxrecalls@inmar.com

By phone: +1 855-670-3976

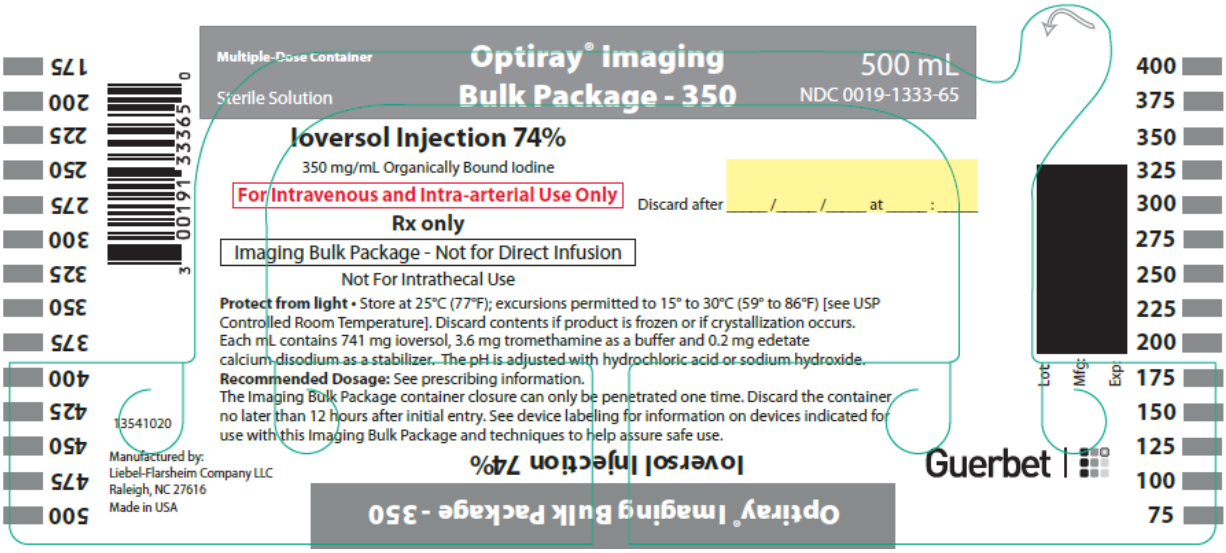
This recall is being made with the knowledge of the Food and Drug Administration.

Your assistance is appreciated and necessary to prevent potential adverse events.

GUERBET sincerely regrets any inconvenience caused to your organization and thanks you for your assistance in helping us to manage this recall.

Garratt W. Ponder, PhD – Interim Site Head of Quality

Enclosure: Product Label



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OPTIRAY 350 IBP, 500mL, Lot 25ZF3670, expiration date May 31, 2027.

Please check ALL appropriate boxes.

Customer Acknowledgement Form

Please complete and return this form *even if you do not have any affected stock.*

DRUG PRODUCT RECALL

Product Description	Batch Number	Expiry Date
OPTIRAY® Imaging Bulk Package 350, 500mL Vial	25ZF3670	May 31, 2027

☐ I have read and understand the recall instructions provided in the attached letter.

☐ I received [ ] units or cases of this product.

☐ I have checked my stock and have quarantined inventory consisting of [ ] units or cases.

☐ Complete the stock disposition details of affected product:

- ☐ returned – specify quantity of vials returned/held for return, date, and method of return _____
- ☐ relabeled – specify quantity and date: _____
- ☐ quarantined - specify quantity of vials: _____
- ☐ used/consumed - specify quantity of vials: _____
- ☐ destroyed - specify quantity of vials, date and method: _____
- ☐ further distributed - specify quantity of vials: _____

Any adverse events associated with recalled product? Yes ☐ No ☐

If yes, please explain:

Please check the appropriate box(es) to describe the nature of your business:

☐ Wholesaler/distributor

☐ Manufacturer

☐ Repacker

☐ Hospital/Medical facility

☐ Other: _____

☐ Medical laboratory

Have you further distributed this product?

☐ Yes (specify quantity) ☐ No

If you have further distributed this product, please confirm you have contacted your consignees and include the date of contact.

☐ Consignees who received the recalled product were contacted on _____[specify date(s) and method].

☐ Consignees have not been contacted. (Please supply names and contact information (email and telephone) of the Consignees).

Organization Name and Address	
Position	
Name	
Email	
Telephone no.	
Date	
Signature	

Return Completed Form by Email or Fax to:

Name	Inmar Rx Solutions (Liebel-Flarsheim's recall processor)
Organization	Liebel-Flarsheim Company LLC, a Guerbet group company
Email	rxrecalls@inmar.com
Fax	817-868-5362
Subject of email	Urgent Recall - OPTIRAY® Imaging Bulk Package 350, 500mL Vial - 25ZF3670