

# CROFAB® REPLACEMENT POLICY

## for Expired Product

*\*Revised Form and Process, 12/1/22*

Facilities who would like to have expired CroFab® ("Product") processed for a Direct free replacement, please follow the instructions below. BTG will ship replacement Product directly to the facility. Please see the reverse side of this page for the terms of this program.

## Direct Replacement Request for Expired Product Form

*\*This form and process is not relevant for customers utilizing Third Party Processors\**

Date of Request: \_\_\_\_\_

Facility Name: \_\_\_\_\_

Product NDC Number: \_\_\_\_\_

Facility Address: \_\_\_\_\_

Lot #/Expiration Date: \_\_\_\_\_/ \_\_\_\_\_

Shipping Attn: \_\_\_\_\_

Quantity of CroFab® Cartons Requesting: \_\_\_\_\_

Facility City: \_\_\_\_\_

*Note: Partial cartons of Product, e.g. 1 vial, will not be accepted.*

Facility State & Zip Code: \_\_\_\_\_

**Facility Certification:** By signing below, I hereby certify that (a) I am able to sign on behalf of my customer; (b) the information above is true and correct; (c) the information above does not include any Protected Health Information (PHI) (as such term is defined in HIPAA); (d) this request is accurate and not fraudulent; (e) that neither I, my practice, nor any practice representative has sought or will seek reimbursement from any source, including private insurance payers and/or any federal or state healthcare program, for any of the Product referenced above; and (f) if my facility does not return the aforementioned quantity of CroFab® to BTG, we will pay at the then-current Wholesale Acquisition Cost (WAC), minus any contracted discounts, for the difference between replacement Product shipped and Product returned, if applicable.

Facility Telephone Number: \_\_\_\_\_

Facility Contact Name (if different): \_\_\_\_\_

Email Address: \_\_\_\_\_

Facility State or Pharmacy License #: \_\_\_\_\_

**\*\*Copy of License Required for First Request\*\***

Facility PO/Debit Memo (required): \_\_\_\_\_

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Position: \_\_\_\_\_

Date: \_\_\_\_\_

### Instructions for Submission of Forms and Return Authorization ("RA") Request for Expired Products:

1. This BTG Replacement Request Form AND a copy of the Facility State or Pharmacy License (if applicable) must be submitted to obtain a Return Authorization ("RA"). The RA will be provided by Inmar RX Solution, Inc. (Inmar), BTG's third-party reverse logistics processor, using one of the methods below:
  - i Log into Inmar's portal at <https://hrm.reskureturns.com/>. Enter GPO Code "BTGSPE" and your DEA number to look up your location (If your location does not populate, please use option ii or iii below). Fill in prompted information, and upload PDFs of both the Replacement Request Form and state license:
  - ii E-mail Replacement Request Form document and state license to [rarequest@inmar.com](mailto:rarequest@inmar.com).
  - iii Fax your Replacement Request Form and state license to Inmar at 817-868-5343.

PLEASE NOTE: All third-party return processors must contact Inmar to initiate an RA.

#### **Customers Contracted with Third Party Processors DO NOT need to submit this form**

For support with any issues related to uploading of forms, please contact Inmar at 800-967-5952, option 3. For questions about this policy or your replacement, please contact BTG at 844-293-0007.

2. Upon receipt of a Return Authorization, the expired product is to be shipped to the processing facility at the following location with the RA label adhered **outside** of each package shipped:

**Inmar RX Solutions, Inc.**  
3845 Grand Lakes Way  
Suite 125  
Grand Prairie, Texas 75050



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BTG Specialty Solutions Center is a trademark of BTG International Ltd.

**CROFab®**  
crotalidae polyvalent immune fab (ovine)

### **Eligible Products for Replacement:**

1. Expired, unused Product purchased by Customers through an Authorized Distributor of Record (“ADR”) or previously replaced under this policy is eligible for replacement when requested for return between the month of expiration and up to 90 days after the Product expires, except as otherwise required by applicable state law.
2. Any expired returns provisions as mandated by state law that conflict shall prevail over this policy.

### **Non-Eligible Products for Replacement:**

1. Partial cartons of Product (e.g. 1 vial) are not eligible and will not be accepted, except as mandated by state law.
2. Product that has been damaged due to conditions beyond the control of the manufacturer, such as heat, cold, water, smoke, fire, or negligence, or not properly stored as outlined by the Prescription Drug Marketing Act (PDMA).
3. Product involved in fire, sacrifice, or bankruptcy sale.
4. Product sold with the specific understanding that it is nonreturnable.
5. Product not purchased through an ADR or bought through other than normal domestic channels of distribution, or product that has not been previously replaced under the policy.
6. Product that has been repackaged or is in packaging other than BTG containers/packages.
7. Product that is obtained in violation of state or federal regulations.
8. Product in which the lot number and/or expiration date is missing, illegible, covered, and/or unreadable on original container.
9. Product damaged in transit, has encountered shipping errors, including shortage or overage claims, or received by a customer from an ADR with less than 12 months dating should be addressed with the ADR that originally shipped the Product.
10. Product returned by, or shipped to BTG from an ADR, rather than directly from a Customer or third-party returns processor will be rejected and destroyed.
11. Product which has been administered to a patient or billed to a patient or third-party payor.

### **Terms**

1. Replacement Product will be shipped after the RA has been fully completed, the expired product has been received and processed by Inmar, and reviewed/confirmed by BTG.
2. Multiple, unused vials can be combined and replaced in the smallest whole number of cartons, if they are all of the same lot, per BTG’s discretion.
3. Product returned to Inmar must be received within sixty (60) days following receipt of RA, or RA can be voided.
4. Any return received that is ineligible for replacement or shipped without an RA will be accepted, but no replacement will be issued, and product will be destroyed at Inmar.
5. Product can be returned via a third-party returns processor, but, the third-party processor must initiate the return via Inmar.
6. Returns shipped “collect” will be refused and returned to sender.
7. Credit will not be issued for returned goods or for administration, shipping, or handling, including third-party processing fees.
8. BTG is not responsible for lost or damaged shipments of returned product(s). Insuring and tracking shipments are the responsibility of the customer.
9. Non-BTG product(s) returned with BTG product(s) will not be the responsibility of BTG. BTG reserves the right to charge customers for any costs incurred to process and destroy such non-BTG product. Any such non-BTG product will not be returned to the customer.
10. BTG reserves the right to inspect all authorized returns prior to issuing replacement and to destroy Products deemed unfit for sale, whether or not they are eligible for replacement.
11. Returns are subject to final count and acceptance by BTG. BTG reserves the right to accept or reject the Product for replacement.
12. A certificate of destruction does not qualify as an acceptable format for Product return.
13. Return requests for instances not addressed above will be reviewed and approved by BTG at BTG discretion on a case-by-case basis. Replacement Product will be determined by BTG at its discretion.
14. BTG reserves the right to change or make exceptions to this policy due to business needs at any time.