SPOILAGE REPLACEMENT PROGRAM INSTRUCTIONS

If the TRODELVY that was prescribed for a labeled indication was spoiled subject to the terms and conditions set forth in the Spoilage Replacement Program Terms, the product may be eligible for replacement through the TRODELVY Spoilage Replacement Program. ***Spoiled Product must be returned, or a Certificate of Destruction , must be provided upon request to Gilead in order to be eligible for replacement.**

REQUESTING REPLACEMENT PRODUCT:

- Complete the Spoilage Replacement Form. Please write legibly and fill in **ALL** required fields. **A Health Care Provider signature is required on the form.**
- **E-mail the form to GileadOncologySupport@gilead.com within thirty (30) days of spoilage occurrence.**
- The replacement request may take up to ten (10) business days to review, provided all documentation is received.
- As applicable or requested, returned Spoiled Product must be received by Gilead **within thirty (30) calendar days of approval.**
- Gilead reserves the right to request a Certificate of Destruction, Proof of Purchase, pictures of the spoiled product, lot number, and serial number if needed.

IMPORTANT GUIDELINES:

- Each request for Spoiled Product replacement requires completion of this form. Replacement is on a case-by-case basis at the sole discretion of Gilead.
- Please retain **all** original product and its packaging for returns processing and return Spoiled Product in accordance with the instructions provided.
- **Gilead does not ship replacement product if the Spoiled Product was prepared for an off-label indication. Gilead does not ship replacement product if ANY portion of the product has been administered.** Gilead can ship replacement product only to licensed healthcare facilities.
- All spoilage requests are subject to review.
- Gilead monitors this program for trends and excessive use and reserves the right to deny product replacement requests.
- Approval of spoilage replacement request is subject to certain limitations and conditions set forth by Gilead, including pictures, product pedigree, and purchase invoices, as requested.
- **Gilead has the right to modify or discontinue the Spoilage Replacement Program at any time without notice.**

For quality or stability related issues, please contact:

Gilead Medical Information (866) 633-4474.

For expired product returns, please contact:

Gilead Trade Operations (800) 939-9009.

Gilead retains the right to make the final decision regarding any spoilage replacement request.

GILEAD

SPOILAGE REPLACEMENT PROGRAM FORM

Email: GileadOncologySupport@gilead.com

Please write legibly and complete ALL information below. Incomplete forms will be denied.

IS THIS THE FIRST TIME A SPOILAGE REPLACEMENT REQUEST HAS BEEN SUBMITTED FOR THIS FACILITY?

☐YES ☐NO

Physician Name:			
Facility Name:			
Street:	City:	State:	Zip code:
Contact Name:	Physician DEA#:	Contact Phone:	
Contact E-Mail:			
Physician License#:	Date of Spoilage:		

In order to distribute/ship a replacement to a pharmacy, DSCSA law requires an active State Board of Pharmacy License for that location. Please provide the name, address, and State Pharmacy License Number where the replacement will be sent. If product was obtained from an affiliated entity, please provide that information below:

Name of Pharmacy:
Address of Pharmacy:
State Pharmacy License#:

Name of Authorized Distributor that was used to purchase Spoiled Product:

PLEASE INDICATE DAYS ON WHICH YOUR OFFICE IS UNABLE TO ACCEPT REPLACEMENT DELIVERY:

Product	Number of Vials	NDC #	Lot # (if available)	Serial # (if available)

THIS SECTION MUST BE COMPLETED:

Reason for Replacement Request:

☐Dropped or Broken ☐ Inappropriate Storage, due to catastrophic event of redundant system failure
☐Reconstituted but **not** administered, due to unforeseen patient circumstances ☐ Error during mixing

IF COLD STORAGE FAILURE, PLEASE NOTE CAUSE:

☐ Catastrophic Event

☐ Redundant system Failure (e.g., battery back-up failure, temperature monitor failure)

☐ Redundant system not in place

THIS SECTION MUST BE COMPLETED:

1. Please provide a detailed explanation on how the spoilage occurred, including any logistical constraints. (Note: For catastrophic events, please provide date, duration, and impact of event):

2. Do you have a redundant system (e.g., battery back-up, temperature monitor, power generator, etc.) in place?

☐Yes (if yes, please list/describe):
_____

☐No

3. If you have a redundant system, if applicable, provide a brief explanation of how it failed:

By checking the boxes below and signing, I acknowledge that I have signing authority for this facility, and that the information provided on this form is true and accurate (All criteria must be met)

☐ **No portion of the Spoiled product has been administered and no portion of the Spoiled Product is intended to be administered to any patient**

☐ **The Spoiled Product was prescribed for an FDA-approved indication**

☐ **No insurance policy coverage exists for replacement of the Spoiled Product**

☐ **No claim or bill has been and no claim or bill will be submitted to any payer or patient for the Spoiled Product and no payment will be received from any payer or patient for any portion of the Spoiled Product**

☐ **The situation resulting in spoilage was beyond the control of the healthcare provider**
☐ **The Spoiled Product has been returned or destroyed**

Healthcare Provider Signature:	Date:
Print Name:	Title:

Sign and Date Here