# TRODELVY® SPOILAGE REPLACEMENT PROGRAM INSTRUCTIONS

If TRODELVY that was prescribed for a labeled indication was spoiled subject to the terms and conditions set forth in the TRODELVY 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 to Gilead** in order to be eligible for replacement.

## REQUESTING REPLACEMENT PRODUCT:

1. Complete the TRODELVY Spoilage Replacement Form. Please write legibly and fill in **ALL** required fields. **A Healthcare Provider signature is required on the form**.
2. E-mail the form to **orderssccs@gilead.com within thirty (30) days of spoilage occurrence**.
3. The request may take up to five (5) business days to review. If approved, further instructions for returning the Spoiled Product to Gilead or completing a Certificate of Destruction will be provided.
4. As applicable, returned Spoiled Product must be received by Gilead **within thirty (30) calendar days of approval**.
5. Replacement of Spoiled Product generally ships within **ten (10)** business days following receipt of returned Spoiled Product or Certificate of Destruction.

## 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 on the Return Authorization form.
- **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 forthby Gilead, including pictures, product pedigree, and purchase invoices, as requested.

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

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 has the right to modify or discontinue the TRODELVY SpoilageReplacement Program at any time without notice.

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# TRODELVY® SPOILAGE REPLACEMENT PROGRAM FORM

Effective Date: 8/23/2021 ☎ Phone: (800) 939-9009 E-mail: ordersccs@gilead.com

**Please write legibly and complete ALL information below or replacement request 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: | | |

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

| Product | Number of Vials | NDC # | Lot # | Serial # and Expiry Dates |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

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

| |
|---|
| |

**IF COLD STORAGE FAILURE, FAILURE DUE TO:**

- ☐ 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 as much detail to explain how the spoilage occurred, including any logistical constraints *(for catastrophic events, 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**

Sign and date here

| | |
|---|---|
| Healthcare Provider Signature: | Date: |
| Print name: | Title: |


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