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1. Introduction

Purpose of the Form

The DSCSA Transaction Information (TI) Response Form is used by pharmaceutical supply chain trading partners or regulatory authorities to request and provide transaction information related to drug products. This form supports investigations into suspect products, illegitimate products, and recalls by tracing ownership and transaction history.

Who Should Use This Guide?

This guide is intended for personnel responsible for filling out the TI Response Form, including compliance officers, regulatory affairs professionals, and supply chain managers.

2. General Instructions

1. **Ensure Accuracy** – All required fields must be completed accurately.
2. **Use Consistent Formatting** – Use standardized formats for dates (YYYY-MM-DD) and identification numbers.
3. **Secure the Form** – Ensure secure transmission of the form, as it contains sensitive product information.

3. Completing the TI Response Form

A. Audit References

- **TI Response ID** (*Required*) – Unique identifier for this response.
- **TI Request ID** (*Required*) – The corresponding request’s unique identifier.
- **TI Request Investigation ID** – Reference ID if part of an ongoing investigation.
- **Timestamp** (*Required*) – Date and time of response submission.

B. Responder Information

- **Person or Department Name** (*Required*) – Name of the individual or department responding.
- **Organization Name** (*Required*) – Name of the responding entity.
- **Phone** (*Required*) – Contact number for inquiries.
- **Email** (*Required*) – Email address of the responder.
- **Responder GLN** – Global Location Number, if applicable.
- **Email Callback Address** – Additional email for follow-up communication.

C. Response Message & Documentation

- **Response Message** – A summary of the response provided.
- **Known 3911 Numbers Related to This Request** – Reference numbers if applicable.
- **Additional Documents Related to This Request** – List of supporting documents.
- **Document Links** – URLs or file paths to related documents.
- **Attached Documents (Names)** – List of attached files.

D. Response Details

Repeat this section for each Request Line Number

- **Request Line Number** (*Required*) – Identifier for the request line item.
- **GTIN or NDC** (*Required*) – Global Trade Item Number (GTIN) or National Drug Code (NDC).
- **Serial Number or Lot** (*Required*) – Serial or lot number of the product.
- **Response Type Requested** (*Required*) – The type of response being provided.
- **Line Number Message** – Notes specific to the request line.

E. Transaction Information (If Requested)

Repeat this section for each transaction record

- **GTIN** (*Required*)
- **NDC** (*Required*)
- **Drug Name** (*Required*)
- **Strength** (*Required*)
- **Dosage Form** (*Required*)

- **Container Size** (*Required*)
- **Number of Containers** (*Required*)
- **Lot Number** (*Required*)
- **Serial Number** (*Required*)
- **Expiration Date** (*Required*)
- **Associated PO** – Purchase order reference.
- **Transaction Statement** (*Required*)
- **Direct Purchase Statement** (*Required*)
- **Date of Shipment** (*Required*)
- **Date of Transaction** (*Required*)

F. Ownership Information

If the requester asked for ownership details, complete the following

Ownership From Information

- **GLN** (*Required*)
- **Company Name** (*Required*)
- **Street Address** (*Required*)
- **City** (*Required*)
- **State** (*Required*)
- **Postal Code** (*Required*)
- **Country Code** (*Required*)
- **TI Request Email Address** (*Required*)
- **TI Request URI Address** (*Optional*)

Ownership To Information

(Same fields as above for the entity receiving ownership)

Ownership History (If Requested)

- **All Known or Last Known Owners** – Complete for all owners meeting the request criteria.
- **Repeat the Ownership Information section for each relevant owner.**

4. Submitting the Form

1. **Review all fields** for accuracy and completeness.
2. **Attach all supporting documents** and verify document links.
3. **Securely send the form** to the requesting trading partner or regulatory authority.

5. Troubleshooting & Common Errors

Issue	Solution
Missing required fields	Verify all required fields are completed before submission.
Incorrect GTIN/NDC format	Use standardized formats as required.
Mismatched transaction dates	Cross-check shipment and transaction records.
Missing attachments	Ensure all referenced documents are attached or linked.

6. Additional Notes

- If errors are identified post-submission, promptly notify the requester.
- Maintain records of responses for compliance audits.

This guide is provided as a reference for completing the DSCSA TI Response Form in compliance with DSCSA requirements.