Training Guide: Completing the DSCSA TI Request PDF Form

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Introduction

The **DSCSA Transaction Information (TI) Request Form** facilitates the secure and structured exchange of transaction information between **pharmaceutical supply chain stakeholders**. This guide provides step-by-step instructions for completing the form accurately and efficiently.

The **TI Request Form** is used to request transaction information or ownership details from a known trading partner. It is commonly utilized for **suspect product investigations, illegitimate product investigations, and product recalls**.

Who Should Use This Guide?

This guide is intended for **pharmaceutical supply chain trading partners and regulatory authorities** responsible for handling DSCSA compliance and ensuring product integrity.

Section 1: Audit References

This section records details for tracking and auditing the request.

- **TI Request ID*** – A unique identifier for the request (assigned by the requester).
- **Investigation ID** – (Optional) A reference number for an internal or regulatory investigation.
- **Timestamp*** – The date and time of submission.

Section 2: Requester Information

The individual or organization requesting the transaction information must provide:

- **Person or Department Name*** – The requester's name or department responsible for the request.

- **Organization Name*** – The requesting entity (e.g., wholesaler, manufacturer, pharmacy).
- **Phone*** – A direct contact number for follow-up inquiries.
- **Email*** – The official email for correspondence.
- **Requester GLN** – (Optional) The **Global Location Number** for unique identification of the organization.
- **Email Callback Address*** – Email to which responses should be sent.

Section 3: TI Request Parameters

This section defines the request details and justifications.

- **Response Type Requested*** – Indicate whether you are requesting full transaction information or specific ownership details.
- **Investigation Reason Attestation*** – Check this box to confirm that the request is related to an **ongoing suspect or illegitimate product investigation**.
- **Investigation Circumstances*** – Provide a brief description of the reason for the request.

If submitting the request on behalf of a regulatory authority, the following must also be completed:

- **Request on behalf of an Authority*** – Check this box if applicable.
- **Authority Person or Department Name*** – Name of the regulatory contact.
- **Authority Organization Name*** – Name of the regulatory agency.
- **Authority Email*** – Contact email for the regulatory authority.
- **Authority Phone*** – Phone number for the authority.

Section 4: Additional Information and Attachments

This section allows for supplemental data that may assist in processing the request.

- **Known 3911 Numbers Related to this Request** – If applicable, provide known **FDA Form 3911 reference numbers** related to this investigation.
- **Additional Documents Related to this Request** – Provide links or attach supporting documents that may assist in validating the request.

Section 5: Product Information Requests

This section allows entry of **multiple product details** within a single request.

For each product, provide:

1. **Request Line Number*** – A sequential number for each product entry.
2. **GTIN or NDC*** – Select either the **Global Trade Item Number (GTIN)** or **National Drug Code (NDC)** and enter the corresponding value.
3. **Serial Number or Lot Number*** – Enter the **serial number** (preferred) or **lot number** (if applicable).
4. **Additional Information** – Any relevant notes on the product or request.

Best Practices for Completing the TI Request Form

- **Ensure Accuracy** – Double-check all details before submitting.
- **Provide Justification** – Clearly outline the reason for the request to avoid delays.
- **Use Consistent Identifiers** – Maintain uniformity in GTINs, NDCs, and serial numbers.
- **Attach Supporting Documents** – If applicable, include documents that support the request.
- **Follow Regulatory Requirements** – Ensure the request complies with **DSCSA guidelines** and trading partner agreements.

Submission and Follow-Up

Once the form is completed:

1. **Verify All Fields** – Ensure all required (*) fields are completed.
2. **Submit to the Trading Partner** – Send the form via the designated communication channel.
3. **Monitor Responses** – Follow up using the contact details provided.

For any questions, contact your DSCSA compliance team or regulatory authority.

This guide ensures that pharmaceutical supply chain partners correctly complete and use the **DSCSA TI Request Form** to maintain **compliance, traceability, and product safety**.