

## **Glossary: DSCSA Transaction Information (TI) Request Terms (Alphabetical Order)**

This glossary is designed to help non-technical employees understand the key elements involved in a DSCSA TI (Transaction Information) Request.

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### **3911 Incident Number List**

*What it is:* A list of incident numbers assigned by the FDA, used during investigations.

*Why it matters:* These numbers track specific cases of illegitimate or suspect product investigations.

### **Additional Information (Base64)**

*What it is:* Files like PDFs or images encoded in text form.

*Why it matters:* Allows attachments to be securely included in the request.

### **Additional Information (Link)**

*What it is:* URLs to documents or files related to the request.

*Why it matters:* Provides supporting documentation via web links.

### **API Callback Address**

*What it is:* A web address to send responses to electronically.

*Why it matters:* Used when automation is available.

### **Authority Information**

*What it is:* Contact information for a health authority (e.g., FDA) if the request is made on their behalf.

*Why it matters:* Enables direct communication with the authority.

### **Callback Address**

*What it is:* Contact point for follow-ups or exceptions.

*Includes:* Email and optionally API.

### **Contact Information**

*What it is:* Contact details for the person or department submitting the request.

*Includes:* Name, organization, phone or email.

### **Credential Presentation**

*What it is:* A digital credential (verifiable credential) confirming the requester's authority.

*Types:* ATP, ATP-Equivalent, or DSCSA Authority.

### **Date/Time of Request (Timestamp)**

*What it is:* When the TI request was sent.

*Why it matters:* Establishes a timeline for compliance.

### **Email Callback Address**

*What it is:* Email address where TI responses or exception notices should be sent.

*Why it matters:* Required for responder communication.

### **GTIN (Global Trade Item Number)**

*What it is:* A 14-digit global product identifier.

*Why it matters:* Used to identify the specific drug product.

### **GLN (Global Location Number)**

*What it is:* A 13-digit number identifying a company's location.

*Why it matters:* Essential for tracking product movement.

### **Investigation Circumstances**

*What it is:* A description of the reason for the TI request.

*Why it matters:* Provides context for responders.

### **Investigation ID**

*What it is:* A custom or UUID number assigned by the requester.

*Why it matters:* Used to track the investigation across systems.

### **Investigation Reason Attestation**

*What it is:* Official reason for the request.

*Options:* Suspect Product, Illegitimate Product, Recall, Compliance Audit, or Health Authority Inspection.

### **Lot Number**

*What it is:* A number that identifies a batch of drug products.

*Why it matters:* Helps with recalls and verification.

### **NDC (National Drug Code)**

*What it is:* A unique FDA-assigned code that identifies a drug.

*Formats:* Vary by manufacturer.

### **On Behalf Of Authority Flag**

*What it is:* A true/false indicator that the request is on behalf of an authority.

*Why it matters:* Determines whether authority contact details are needed.

### **Person or Department Name**

*What it is:* The name of who to contact about the request.

*Why it matters:* Clarifies responsibility.

### **Phone Number**

*What it is:* The phone contact for the requester.

*Why it matters:* Provides another way to reach out.

**Product ID**

*What it is:* Identification of the drug by GTIN or NDC.

*Why it matters:* Identifies the product being investigated.

**Recall Depth**

*What it is:* Indicates how far down the supply chain the recall applies.

*Options:* Wholesale Distributor, Pharmacy, or Patient.

**Recall Request Level**

*What it is:* Specifies whether recall is by Lot or Serial Number.

*Why it matters:* Helps responders target the correct product.

**Request ID**

*What it is:* A globally unique identifier (UUID) for the entire request.

*Why it matters:* Used to track and match responses.

**Request Line Number**

*What it is:* A line identifier for a specific item in a multi-product request.

*Why it matters:* Allows line-level tracking.

**Requester GLN**

*What it is:* The GLN of the organization submitting the request.

*Why it matters:* Identifies the requesting party.

**Response Type Requested**

*What it is:* Indicates what the requester wants in return.

*Options:* Transaction Information, All Known Owners, or Last Known Owner.

**Serial Number**

*What it is:* A unique identifier for a single product unit.

*Why it matters:* Allows item-level tracing.

**TI Request Set**

*What it is:* The complete data structure that holds all TI request information.

*Why it matters:* It's the container for the request.

**Tracing Model Set Version**

*What it is:* Identifies the version of the model being used.

*Why it matters:* Ensures compatibility and consistency.

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This glossary can be used in training or as a reference for reviewing and submitting DSCSA TI Requests.

*End of Glossary*