

Glossary: DSCSA Transaction Information (TI) Response Terms (Alphabetical Order)

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

3911 Incident Number

What it is: An FDA-assigned number for investigations or reported issues.

Why it matters: Helps track problem cases.

Additional Information (Links or Files)

What it is: Extra documents or links related to the product or request.

Format: May be links or encoded files (PDFs, images).

Callback email Address

What it is: Where to send follow-ups or exception reports.

Formats: May include email or API addresses.

Company mailing Address

What it is: The physical address of the company involved in the TI record.

Why it matters: Identifies the source or recipient of the drug shipment.

Company Name

What it is: The legal name of the company listed in the TI record.

Why it matters: Ensures clear identification of supply chain entities.

Contact Information

What it is: The name, phone, and/or email of a contact person.

Why it matters: Used if there are follow-up questions about the response.

Container Size

What it is: The size of the product container (e.g., 100 tablets).

Why it matters: Helps verify product and package specifics.

Credential Presentation

What it is: A digital credential proving the responder is authorized.

Why it matters: Verifies the response comes from a legitimate source.

Date of Shipment / Date of Transaction

What it is: When the drug was shipped or sold.

Why it matters: Establishes the timeline of ownership.

Direct Purchase Statement

What it is: Notes if the product was purchased directly from the manufacturer.

Why it matters: Helps verify authenticity.

Dosage Form

What it is: How the drug is administered (e.g., tablet, capsule, injection).

Why it matters: Ensures accurate product understanding.

Drop Ship Indicator

What it is: Shows whether the drug was shipped directly to a third party.

Why it matters: Affects who is listed as the buyer and seller.

Email Callback Address

What it is: The email address where exceptions or questions about the TI response can be sent.

Why it matters: Facilitates fast follow-up.

Expiration Date

What it is: The date after which the drug should not be used.

Why it matters: Ensures safety and compliance.

GTIN (Global Trade Item Number)

What it is: A 14-digit number identifying the product globally.

Why it matters: Helps uniquely identify the drug.

GLN (Global Location Number)

What it is: A 13-digit number identifying the location of a company.

Why it matters: Used in the supply chain to identify sender/receiver locations.

Lot Number

What it is: A batch number used to identify a group of drugs.

Why it matters: Important for recalls and tracking production.

NDC (National Drug Code)

What it is: A unique identifier assigned by the FDA.

Why it matters: Required for drug identification in the U.S.

Number of Containers

What it is: Always "1" for each serialized product unit in a TI response.

Why it matters: Indicates package-level tracing.

Ownership Information

What it is: A list of past owners or the last known owner of the product.

Why it matters: Helps verify the drug's movement through the supply chain.

Ownership Information Notes

What it is: Additional notes regarding the ownership information provided in a TI Response.

Why it matters: The Responder uses it to add context to the ownership information. For example, a returned item was subsequently sold to another customer.

PO (Purchase Order) Associated with TI

What it is: A reference to the order tied to the shipment.

Why it matters: Helps match the shipment to internal business records.

Phone Number

What it is: Contact number for reaching someone about the request or response.

Why it matters: Useful for clarifying urgent issues.

Product Data

What it is: Details about the drug such as GTIN, name, dosage, and strength.

Why it matters: Describes the product in the TI response.

Product ID (GTIN or NDC)

What it is: A number identifying the drug product.

Why it matters: Tells exactly what drug is being referenced.

Production Data

What it is: Includes lot number, serial number, and expiration date.

Why it matters: Helps track product origin and integrity.

Responder GLN

What it is: The GLN of the company sending the TI response.

Why it matters: Identifies the source of the response.

Request ID

What it is: The unique number from the original TI request.

Why it matters: Ensures the response is tied to the correct request.

Request Line Number

What it is: A number identifying a specific item or product in the TI request.

Why it matters: Used to match individual requests to their responses.

Request Type (Response Type Requested)

What it is: Specifies the information being asked for.

Options include: Transaction Info, All Known Owners, or Last Known Owner.

Response ID

What it is: A unique number that identifies the TI response.

Why it matters: Helps match the response to the original request.

Response Message

What it is: Free-text explanation or notes from the responder.

Why it matters: Used when formal data isn't available or to give more context.

Serial Number

What it is: Unique number printed on the product to track it.

Why it matters: Needed to trace individual packages.

State, City, Postal Code, Country Code

What it is: Part of the company address.

Why it matters: Helps precisely locate parties involved in the TI.

Strength

What it is: The potency of the drug (e.g., 500mg).

Why it matters: Ensures proper treatment and product use.

TI Request Responses

What it is: Contains responses to one or more product tracing requests.

Why it matters: Bundles related responses together.

TI Response

What it is: A message sent in reply to a DSCSA Transaction Information request.

Why it matters: Confirms supply chain data about a drug, helping trace its path.

Tracing Model Set Version

What it is: The version number of the model used to structure the TI response.

Why it matters: Ensures all parties use the same format and rules.

Transaction Information

What it is: Details about a sale or shipment of the drug.

Includes: Who sold it, who bought it, dates, and shipment details.

Transaction Information Notes

What it is: Additional notes regarding the transaction information provided in a TI Response.

Why it matters: The Responder uses it to add context to the transaction information. For example, a returned item was subsequently sold to another customer.

Transaction Statement

What it is: A required DSCSA statement included with the product's info.

Why it matters: Legally affirms the product's legitimacy.

This glossary can be used as part of employee training or kept on-hand for reference when reviewing or creating DSCSA TI Responses.

End of Glossary