

Concepts and Terminology for FDA’s Public Meeting Series
Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act
 (December 5-6, 2017, February 28, 2018)

*The following terminology is provided to help facilitate discussions at this series of public meetings only and **should not** be interpreted as legal or regulatory definitions or guidance.*

Advance Ship Notice (ASN)	ASN is an Electronic Data Interchange (EDI) transaction used to provide the receiving company with advance data on shipments
Aggregation	Aggregation is the process of building a relationship between unique identifiers assigned to packaging containers
Attribute	Properties or capabilities of the system that would allow it to meet at least one of the stated system goals
Centralized System	System where data from all stakeholders is stored in one central database
Commission [of a serial number]	Creation of a serial number for a package or homogenous case of product that is active in the pharmaceutical distribution supply chain
Data Architecture	A set of rules, policies, standards and models that govern and define the type of data collected and how it is used, stored, managed and integrated within and between organizations and respective systems.
Data Management	Standardized mechanisms that supply chain participants use to capture, maintain, protect, and utilize product tracing data to facilitate product tracing and verification. These mechanisms may include information for ensuring compliance of and accountability for established processes, as well as corrective action if these processes are not followed.
Decentralized System	System where data is stored across multiple databases.
Decommission [of a serial number]	Changing of the status of an active serial number to an inactive status because the product is no longer active in the supply chain (i.e., destroyed, expired) or to impede distribution or to enable verification of the product identifier
Electronic Data Interchange (EDI)	EDI is the computer-to-computer electronic communication of purchase orders, invoices, shipment notices, other key business to business messages based on defined industry standards.

Electronic Product Code Information Services (EPCIS)	EPCIS is a standard developed by GS1 that defines a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain.
Exceptions Handling	The process for handling discrepancies between product and product tracing information.
Inference	Inference involves examining information for a higher level of packaging to infer information about the next level packaging and its contents.
Interoperability	The ability of systems to exchange information accurately, efficiently, and consistently in a usable format.
Invoice	Invoice is an itemized bill that identifies the seller/payee and purchaser/payer. Invoices may also contain additional information.
Master Product Data	Information that is associated with a product that remains unchanged as it is distributed (e.g. the product description).
Packing slip	A list of products included with the shipment. A packing slip usually includes the names and addresses of the shipping party and the receiving party as well as a control or tracking number.
Semi-Centralized System	A system where data is stored in a few select databases.
Serialization	The process of applying a unique serial number to each package or homogenous case of product. The serial number is part of the product identifier that is required under section 582 of the FD&C Act.
Scalability	The ability of a system to accommodate growth in its operational workload and continue to function at an acceptable level of performance.
Status	The description of the package as it is distributed through the supply chain (e.g., recall in process, in transit, destroyed, dispensed, stolen, etc.).
Web portal	A secure single point of internet access utilized by different stakeholders to deposit and retrieve information.