CARES Act Drug Amount Reporting Examples

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Outline

- Key Terminology Used For Reports
- Finished Dosage Form (FDF) Example
- Active Pharmaceutical Ingredient (API) Example
- Drugs For Further Processing Example
- Kit With Multiple Components Example

Key Terminology Used for Reports

- Single Level Packaging
- Multilevel Packaging
- Outermost Package
- Innermost Package
- Manufactured and Released

Finished Dosage Form (FDF) Examples (1/6)

- Single Level Packaging

Item Code	Package description
12340-567-89	100 TABLETS in 1 BOTTLE

Single Level Package

- Quantity Released Reporting Example

	Outermost package			Innermost package			
NDC	Quantity released	Quantity distributed (non-U.S.)	Package type	Quantity released	Quantity distributed (non-U.S.)	Package type	Market unknown
12340-567-89	2000		BOTTLE				

Finished Dosage Form (FDF) Examples (2/6)

- Multi-Level Packaging, only the outermost packaging has been assigned an NDC)

Item code	Package description
12340-567-01	96 CARTONS in 1 CASE
	5 BOTTLES in 1 CARTON
	60 CAPSULES in 1 BOTTLE

Outermost Package

Innermost Package

- Quantity Released Reporting Example

	Outermost package			Innermost package			
NDC	Quantity released	Quantity distributed (non-U.S.)	Package type	Quantity released	Quantity distributed (non-U.S.)	Package type	Market unknown
12340-567-01	20		CASE	9600		BOTTLE	

Finished Dosage Form (FDF) Examples (3/6)

- FDF - Multi-Level Packaging with multiple NDCs

Item code	Package description
12340-999-02	3 POUCHES in 1 CARTON
12340-999-01	5 BLISTER PACKS in 1 POUCH
	21 TABLETS in 1 BLISTER PACK

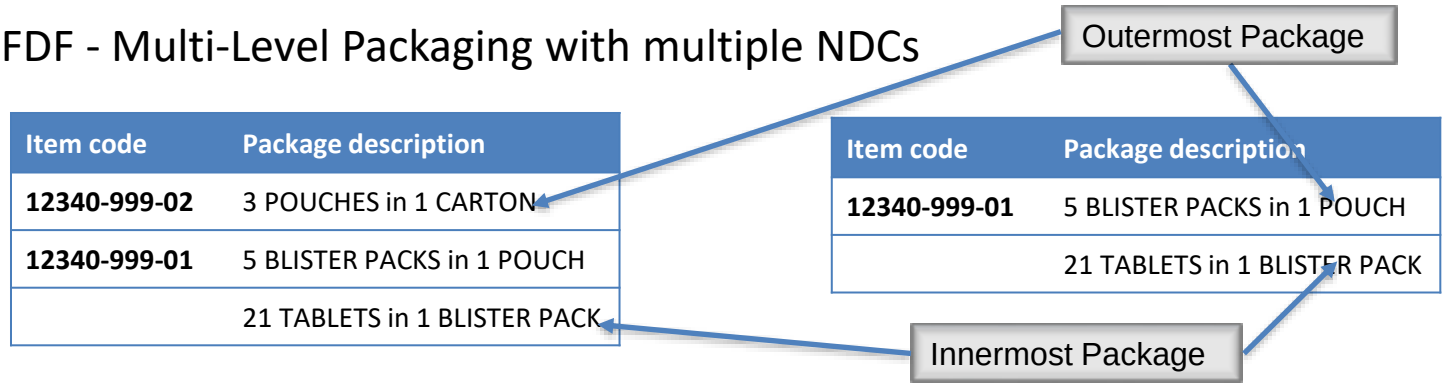
Outermost Package

Innermost Package

	Outermost package			Innermost package			
NDC	Quantity released	Quantity distributed (non-U.S.)	Package type	Quantity released	Quantity distributed (non-U.S.)	Package type	Market unknown
12340-999-02	20		CARTON	300		BLISTER PACK	

Finished Dosage Form (FDF) Examples (4/6)

- FDF - Multi-Level Packaging with multiple NDCs



	Outermost package			Innermost package			
NDC	Quantity released	Quantity distributed (non-U.S.)	Package type	Quantity released	Quantity distributed (non-U.S.)	Package type	Market unknown
12340-999-02	20		CARTON	300		BLISTER PACK	
12340-999-01	500		POUCH	2500		BLISTER PACK	

Finished Dosage Form (FDF) Examples (5/6)

- FDF - Multi-Level Packaging

Item code	Package description
12340-567-01	96 CARTONS in 1 CASE
	5 BOTTLES in 1 CARTON
	60 CAPSULES in 1 BOTTLE

Outermost Package

Innermost Package

- Quantity Released and Distributed Reporting Example

	Outermost package			Innermost package			
NDC	Quantity released	Quantity distributed (non-U.S.)	Package type	Quantity released	Quantity distributed (non-U.S.)	Package type	Market unknown
12340-567-01	20	3	CASE	9600	1440	BOTTLE	

Finished Dosage Form (FDF) Examples (6/6)

- Multi-Level Packaging (FDF)

Item code	Package description
12340-567-01	96 CARTONS in 1 CASE
12340-567-02	5 BOTTLES in 1 CARTON
	60 CAPSULES in 1 BOTTLE

Outermost Package

Innermost Package

- Quantity Released with Market Unknown Reporting Example

	Outermost package			Innermost package			
NDC	Quantity released	Quantity distributed (non-U.S.)	Package type	Quantity released	Quantity distributed (non-U.S.)	Package type	Market unknown
12340-567-01	10		CASE	4800		BOTTLE	YES

Active Pharmaceutical Ingredient(API) Examples (1/2)

- API Single Level Packaging

Item Code	Package description
12340-567-89	200 KG in 1 DRUM

Single Level Package

- Quantity Released Reporting Example

	Outermost package			Innermost package			
NDC	Quantity released	Quantity distributed (non-U.S.)	Package type	Quantity released	Quantity distributed (non-U.S.)	Package type	Market unknown
12340-567-89	20		DRUM				

Active Pharmaceutical Ingredient(API) Examples (1/2)

- API - Single Level Packaging

Item Code	Package description
12340-567-89	200 KG in 1 DRUM

Single Level Package

- Quantity Released and Market Unknown Reporting Example

	Outermost package			Innermost package			
NDC	Quantity released	Quantity distributed (non-U.S.)	Package type	Quantity released	Quantity distributed (non-U.S.)	Package type	Market unknown
12340-567-89	20		DRUM				YES

Drugs For Further Processing Example

- Drugs For Further Processing

Item Code	Package description
12340-567-89	1440000 CAPSULE, GELATIN COATED in 1 DRUM

Single Level Package

- Quantity Released Reporting Example

	Outermost package			Innermost package			
NDC	Quantity released	Quantity distributed (non-U.S.)	Package type	Quantity released	Quantity distributed (non-U.S.)	Package type	Market unknown
12340-567-89	3		DRUM				

Kit With Multiple Components Example

- Kit with multiple components

Item code	Package description
12340-567-01	1 in 1 CARTON

Part Number	Package quantity
1	Drug 1 (1 VIAL, MULTI-DOSE)
2	Drug 2 (1 VIAL, SINGLE-DOSE)
3	Drug 3 (1 Packet)

- Quantity Released Reporting Example

	Outermost package			Innermost package			
NDC	Quantity released	Quantity distributed (non-U.S.)	Package type	Quantity released	Quantity distributed (non-U.S.)	Package type	Market unknown
12340-567-01	30		CARTON				

Summary

- This presentation has provided insights on how registrants should submit CARES Drug Amount Report with emphasis on critical data elements like Quantity Released, Quantity distributed (Non-US), Market Unknown
- Examples included the following
  - Finished Dosage Form (FDF)
  - Active Pharmaceutical Ingredient (API)
  - Drugs for further processing
  - Kit with multiple components

Resources

- Coronavirus Aid, Relief, and Economic Security Act (CARES Act) Drug Shortage Mitigation Efforts weblink: https://www.fda.gov/drugs/drug-shortages/coronavirus-aid-relief-and-economic-security-act-cares-act-drug-shortage-mitigation-efforts
  - FDA Draft Guidance for Industry Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act
  - Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide
  - NextGen Registration Guide, User Reference Guide, CSV template and Instructions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