U.S. FOOD & DRUG ADMINISTRATION

Should this drug package or case have a product identifier under the

Drug Supply Chain Security Act?

Determine whether the drug is a product covered under the Drug Supply Chain Security Act (DSCSA). Covered products are defined as human prescription drugs in finished dosage form and are required to have a product identifier on each package. Most prescription drugs are covered under the law, but there are a few exceptions.

YES, the product is covered under DSCSA

NO, the product is not covered under DSCSA

Product identifier is not required.

Which trading partner are you under DSCSA?

I'm a manufacturer selling product

As of 11/27/2018 – product identifier is required.

Products packaged before 11/27/18 do not need product identifiers and can continue to move through the supply chain.

See Grandfathering Policy and Product Identifier Compliance Policy

I'm a repackager selling product

As of 11/27/2018 – product identifier is required.

Products packaged before 11/27/18 do not need product identifiers and can continue to move through the supply chain.

See Grandfathering Policy

I'm a repackager buying product

Do you have documentation that the product was packaged by a manufacturer or other repackager before 11/27/2018?

YES

The product is grandfathered. You can buy it without a product identifier.

NO

The product is not grandfathered. It should have a product identifier unless it is subject to a waiver or exemption. Confirm with the product manufacturer or other repackager.

See Grandfathering Policy

I'm a wholesale distributor or dispenser buying or selling product

Do you have documentation that the product was packaged by a manufacturer or repackager before 11/27/2018?

YES

The product is grandfathered. You can buy and sell it without a product identifier.

NO

The product is not grandfathered. It should have a product identifier unless it is subject to a waiver or exemption. Confirm with the product manufacturer or repackager.

See Grandfathering Policy

If you are still unsure whether a prescription drug should have a product identifier, contact the manufacturer or repackager.

For definitions in the Federal Food, Drug, and Cosmetic Act, see section 581(13) for product, section 581(14) for product identifier, 581(7) for homogenous case and section 581(11) for package. See the Grandfathering Policy for the type of documentation that would identify if a product is grandfathered.