The FDA has Spoken: Grandfathering Guidance has been released!

The FDA released the Grandfathering policy on November 27, 2017. Although this guidance is exactly two years late (Based on the DSCSA timeline), it provides clear direction on the grandfathering policy.

Typically, FDA guidance documents express the FDA's suggestions and recommendations which do not establish legally enforceable responsibilities. However, Congress granted authorization, through the DSCSA, to the FDA to establish legally enforceable responsibilities via this grandfathering guidance (*once published*).

Let's review a few key terms relevant to this matter:

1. ***"In the Pharmaceutical Supply Chain"*** – a package or homogenous case of product is "in the pharmaceutical distribution supply chain" if it was packaged by the product's manufacturer before November 27, 2018. This is not to be confused with the manufacturing date.
2. ***EPCIS*** – Electronic Product Code Information Services (EPCIS) is the EPCglobal standard for capturing and communicating the business events for tracking and tracing products within an enterprise and across the supply chain. EPCIS is a standard that defines interfaces for representation and exchange of data.
3. ***Product identifier*** – The term `product identifier' means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

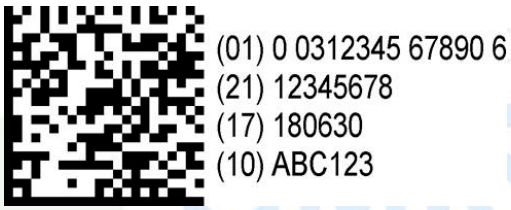

Figure 1 - Product Identifier Example

4. ***Shipping Event*** – an EPCIS transaction in which one entity sends the Product Identifier data corresponding to the physical packaging within the shipment to the receiving party.
5. ***Standardized numerical identifier*** – The term `standardized numerical identifier (SNI)' means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

Figure 2 - Standardized Numerical Identifier Example

6. **T3** – Refers to the three DSCSA definitions of Transaction History, Transaction Information and Transaction Statement. The exchange of this information amongst trading partners is required as part of the Phase I 2015 DSCSA requirements, also known as the Lot Traceability requirements.
7. ***Verify*** – `The term `verification' or `verify' means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier (SNI) or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582.
8. ***Validate*** – The FDA, in this guidance, clarifies the distinction between the validation of 'Lot Traceability' data and verification of serialized data. Within this guidance, validate means to confirm Transaction History and Transaction Information.

1. **The grandfathering policy states that a package or homogenous case of product is "in the pharmaceutical supply chain" if it was packaged by the product's manufacturer or repackager before 11/27/2018.**
2. **Any product packaged before 11/27/18 is thereby exempted from product identifier requirements including the affixing of the product identifier to the package.**
3. **Subsequently, any verification requirements (of product identifier for either investigation of suspect product, or for saleable returns) are exempted for any product that does not have a product identifier affixed.**

One key note, is that manufacturers must have documentation to prove the product has been packaged into its final state prior to 11/27/18.

The guidance puts forth a few examples of how to prove this, such as batch records and date of sale (e.g. within T3 data). Further, the guidance does provide flexibility around proving your company's product was "in the pharmaceutical supply chain," by 11/27/18.

The document also specifies that, "manufacturers retain packaging date information in the ordinary course of business and as a part of batch recordkeeping, and they should provide the packaging date to subsequent trading partners if they request it." Therefore, proof of exemption by a manufacturer during an inspection could be a packaging batch record with the date of packaging completion prior to 11/27/18. The draft guidance also highlights that the transaction statement can serve as proof of exemption for downstream trading partners.

Grandfathering Exemptions Broken Down by Supply Chain Role:

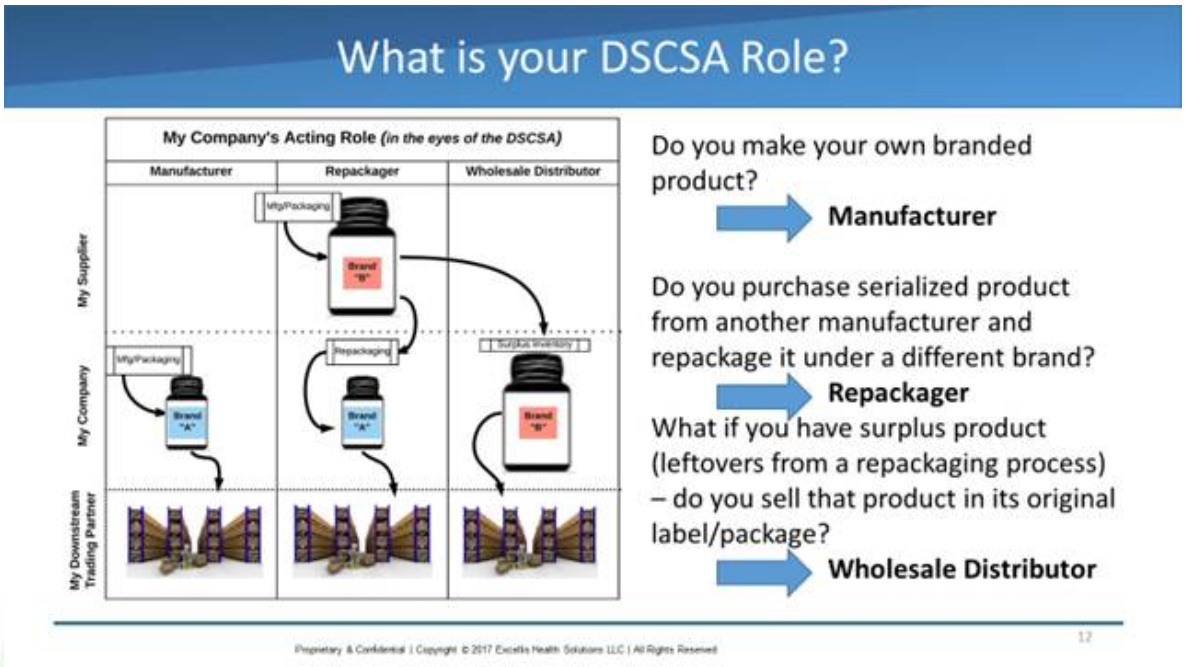

Figure 3 - What is your DSCSA Role

Note: In all the below scenarios, for the product to be exempt, it requires documentation that serves as proof that the product in the transaction was in the pharmaceutical supply chain by 11/27/2018.

Manufacturers:

Where product has been "in the pharmaceutical supply chain" prior to 11/27/18 and no product identifier has been affixed to the package, manufacturers are:

1. Exempted from (*suspect/illegitimate product scenario*) verification requirements *of the product identifier* for product in their possession
2. Required to perform validation of Transaction History and Transaction Information (*in their possession*) if Trading Partner, or FDA, requests
    - Manufacturers are also still required to respond to Trading Partners within 24hrs

Wholesale Distributors:

Where product has been "in the pharmaceutical supply chain" prior to 11/27/18 and no product identifier has been affixed to the package, wholesale distributors are:

1. Exempted from the requirement to engage in transactions only involving serialized product (originally, a *11/27/19 deadline*)
2. Exempted from Product identifier verification (*illegitimate product scenarios)* requirements beginning 11/27/19
3. Still required to validate any applicable Transaction History and Transaction Information in their possession upon request.

Dispensers:

Where product has been "in the pharmaceutical supply chain" prior to 11/27/18 and no product identifier has been affixed to the package, dispensers are:

1. Exempted from the requirement to engage in transactions involving only serialized product (originally, a 11/27/20 deadline)
2. Exempted from Product identifier verification (*illegitimate product scenarios)* requirements beginning 11/27/20
3. Still required to:
    - Verify lot number of suspect product
    - Validate TH and TI in possession and otherwise investigate if it is illegitimate
    - Dispensers must comply with all other requirements of section 582

Repackagers:

Where product has been "in the pharmaceutical supply chain" prior to 11/27/18 and no product identifier has been affixed to the package, Repackagers are:

1. Allowed to accept ownership of non-serialized packages/homogenous cases post 11/27/18, but must serialize product before further transferring ownership after that date (Repackagers, like manufactures, are required to serialize by 11/27/2018)
2. Exempted from Product identifier verification (*illegitimate product scenarios*) requirements beginning 11/27/18
3. Still required to validate Transaction History and Transaction Information in possession and otherwise uphold investigation requirements

Saleable returns (*packages and homogenous cases*):

1. Saleable returns (verification of the Product Identifier of saleable returned package or sealed homogeneous case intended for further distribution) timeline is confirmed; 11/27/17 for manufacturers, 11/27/18 for Repackagers, and 11/27/19 for wholesale distributors
2. Manufacturers, Wholesale Distributors, and Repackagers are exempted from returns verification requirements for product that does not bear a product identifier and was in the pharmaceutical supply chain before 11/27/2018.
3. Once your company's return requirements have come into effect, supply chain entities are required to validate (*associate*) Transaction Statement and Transaction Information of the product being returned in order to resell that returned product.
4. Manufacturers and Repackagers are not required to add the product identifier to salable returns before re-distribution, as long as the product was initially in the Pharmaceutical Supply Chain prior to 11/27/18.

Key Takeaways:

- **All product packaged after 11/27/18 must be serialized.** This FDA guidance says that all packaging lines (both manufacturers and repackagers) must be ready to serialize the saleable unit and homogenous cases by 11/27/2018.

- **It is acceptable to build non-serialized inventory**, provided that shareable information exists to serve as documented proof that the product was "in the pharmaceutical supply chain" prior to 11/27/18. Manufacturers and repackagers should be prepared to share the packaging date with trading partners.

- **There are NO exemptions on Lot Traceability requirements**. Instead, the draft Grandfathering guidance further drives home the T3 requirements. The Manufacturer requirements to send all T3 information electronically by 11/27/17 is still in effect.

- In downstream trading partner verification scenarios… no 'product identifier = no verification'. Makes sense, simply because trading partners are not able to conduct the verification without the product identifier. BUT, don't forget, as specified in the FDA Product Identifier Non-Enforcement guidance, once a product is serialized, ***all verification requirements are in effect!***
  - The verification process is demonstrating that 2D & Human readable information on the physical package *corresponds* with the Product Identifier applied by the manufacturer.
  - If your company is using EPCIS, there are a few ways to verify a suspect product:
    - Query the Product Identifier data in question against the Manufacturers Ship Event.
    - Request verification from the manufacturer. The manufacturer, under their obligation to respond to requests for information, will query the product identifier against their Commissioning Event data.
      - ❖ This will likely be a manual process until a time in which supply chain partners are sharing shipment specific EPCIS data (*DSCSA interoperable system requirement*). It may be prudent to develop these processes prior to your first request for information.
      - ❖ The below diagram illustrates the discussed verification processes

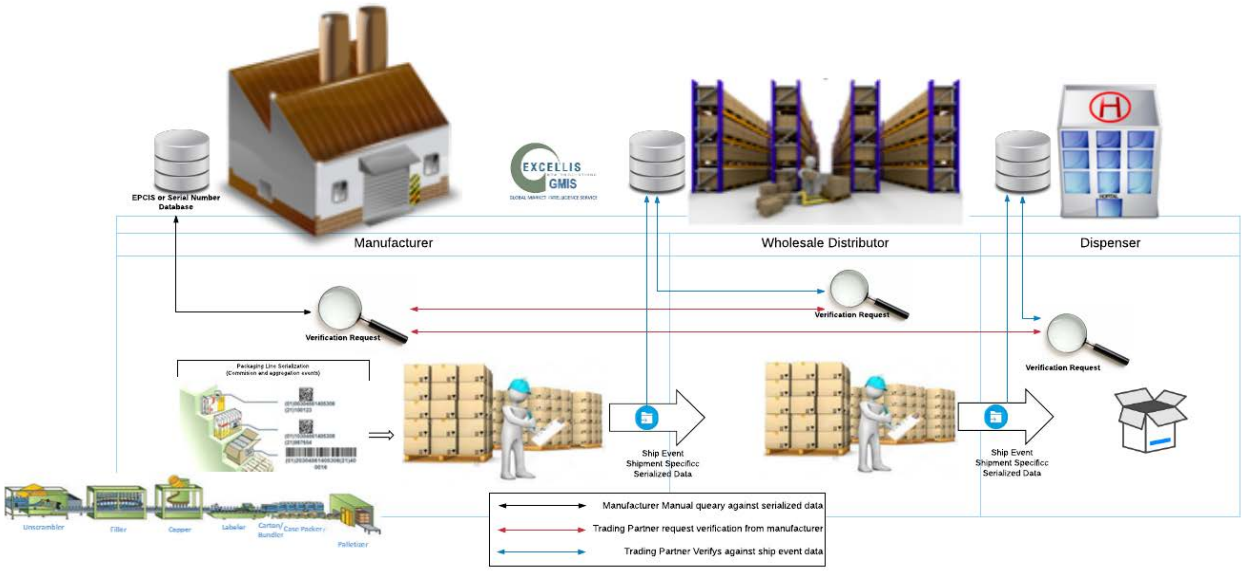

Figure 4 - Product Identifier Verification Diagram

Here is a look at the overall effect of the Grandfathering & Non-enforcement Guidance on the serialization phased approach timeline:

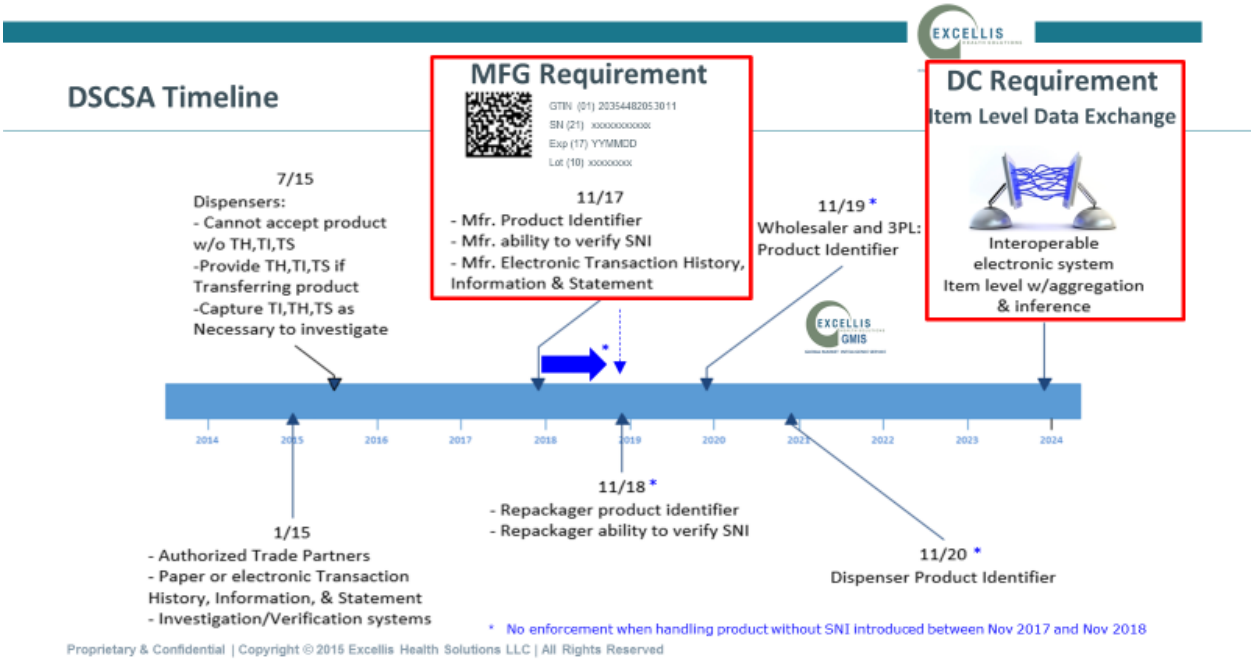

Figure 5 - Adjusted DSCSA Timeline

Contact the FDA

- The FDA is accepting comments and suggestions for 60 days.
- Submit electronic comments to https://www.regulations.gov.
- Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.
- For questions regarding this draft document contact (CDER) Office of Compliance at 301-796- 3100 or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240- 402-8010, or drugtrackandtrace@fda.hhs.gov.

Contact Excellis Health Solutions

- Please reach out with any questions to GMIS@excellishealth.com

Links:

FDA Grandfathering Guidance:
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM586509.pdf

FDA Product Identifier Compliance Policy (non-enforcement guidance) – https://excellishealth.com/wp-content/uploads/2017/07/USA_FDACompliancePolicy.pdf

Excellis Health Solution Global Market Intelligence Service Market summary: https://excellishealth.com/global-serialization-regulation/