

FDA Announces Enforcement Delay for Manufacturers But Law Still in Effect

On June 30, 2017, the FDA published draft guidance regarding DSCSA that included information about a one-year enforcement delay for manufacturers that will be in effect from November 27, 2017 through November 26, 2018. The enforcement delay does not change the timing of the law itself, so it is important that you and your trade partners understand exactly what the new guidance means.

DSCSA requires manufacturers to affix or imprint a unique product identifier at both the package level and at the secondary homogenous-case level before the product enters the supply chain. In addition, manufacturers must verify serialized drug product at the package level within 24 hours when receiving a verification request by the FDA, when requested by trading partners as part of a suspect product investigation, or as part of verifying the identity of saleable returns.

Has the DSCSA law been delayed?

No. The FDA guidance states that it will exercise “enforcement discretion” regarding the federal requirements for product identifiers until next year. This does not delay the law—it will still go into effect on November 27, 2017.

Does enforcement discretion mean that there’s no chance of penalties until November 2018?

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No. Because DSCSA will be the law in November, non-compliance can still be penalized. The FDA reserves the right to inspect and penalize companies if it so chooses, although it will not go out of its way to enforce DSCSA during the period of delay.

Under what circumstances could my company be penalized during the period of enforcement discretion?

Because the law will take effect on November 27, 2017, companies could be penalized should an incident occur in the supply chain that requires an investigation and the FDA finds that a company's negligence to comply with the law on time has contributed to the incident. In other words, companies are still liable for actions that have legal consequences. During the period of enforcement discretion, the FDA is unlikely to inspect and penalize companies for no reason at all. But if an incident involving a company occurs and there is an impact on patient safety, companies that are not in compliance during the enforcement discretion can be investigated by the FDA and could be held accountable for not complying with the law.

How does enforcement discretion apply specifically for manufacturers?

If you're a manufacturer, the FDA has indicated that between November 27, 2017, and November 26, 2018, it does not plan to inspect your operation at random and take action if you are not currently:

- Correctly affixing or imprinting a product identifier on each package of homogenous case of drug product prior to introducing it into commerce.
- Performing verification of suspect product or if a verification request is received.
- Performing verification at the request of a trade partner.
- Performing verification of a saleable returned product.

What does the period of enforcement discretion mean for downstream

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trade partners?

If you are a repackager, wholesale distributor, or dispenser that buys or sells products from a manufacturer, you may be wondering about receiving and verifying product that has been introduced into commerce by the manufacturer between November 27, 2017 and November 26, 2018 without having a serialized product identifier. The FDA has reinforced that they do not intend to take action against you if you accept ownership of such product on or after your respective serialization deadlines in November 2018, 2019, or 2020, or if you do not use a product identifier to verify such product as may be required.

This compliance policy does not affect the separate requirement that repackagers have to affix or imprint a product identifier on products beginning November 27, 2018.

Why is the FDA instituting enforcement discretion for a year?

A number of manufacturers and their trade partners have been expressing concerns about industry readiness to meet the initial manufacturer's serialization deadlines. Based on that feedback and with a desire to minimize potential disruptions in the medicine supply chain, the FDA decided to provide some additional flexibility for the industry as it continues its push towards full compliance with DSCSA.

Does the delay impact lot-level DSCSA?

No. This enforcement delay does not apply to lot-level requirements under DSCSA. Manufacturers are still required to validate T3 of suspect product or for a verification request when it is received from the FDA, or if a trade partner has possession of suspect product.

What about serialized product that goes into the supply chain between November 27, 2017 and November 26, 2018?

The FDA stated that this new compliance policy does not apply to any other

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provisions of section 582(b)(4), the verification provisions. For product already containing a product identifier that has been introduced into the supply chain, the FDA expects manufacturers and downstream trading partners to use it in verification.

What does the delay mean for grandfathered product?

The FDA stated in this compliance policy guidance that they intend to publish additional guidance describing the FDA's thinking on "grandfathering product," essentially product not labeled with a product identifier that is in the supply chain on or after subsequent effective dates in DSCSA for serialized product management. The FDA will then clarify the language in this policy with that of grandfathered products.

You can download a copy of the actual FDA DSCSA Compliance Policy Guidance for Industry.

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