FDA Extends November 27, 2023 Deadline for Drug Supply Chain Security Act (DSCSA) Changes by One Year

In July, the European Union Commission published their **"Proposal for Regulation of the European Parliament and of the Council"** – amending Regulation EU 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury as it regards to dental amalgam and other mercury added products, as subject to manufacturing, import and export restrictions.

The Food and Drug Administration (FDA), however, just announced a year-long compliance moratorium on this implementation date so to give trading partners – manufacturers, wholesale distributors, dispensers and repackagers involved in the prescription drug supply chain – additional time to develop and implement appropriate systems and processes for interoperable electronic package tracing and otherwise to achieve high levels of supply chain security. **The new compliance implementation date is November 27, 2024.**

This means that the FDA will defer enforcement efforts for one year of the following:

1. The requirement that transaction information include the "product identifier" (i.e., standardized number consisting of the national drug code, serial number, lot number and expiration date). Any product introduced into commerce before November 27, 2024 will remain compliant after that date and through the product's expiry even though the drug, at the product level, does not have a product identifier.
2. The requirement that transaction information and statements be exchanged in a secure, interoperable, electronic manner.
3. The requirement that a company covered by the DSCSA implement systems and processes to verify products at a package level. Also deferred are the requirements that such systems and processes be able to interact with other trading partners and with the FDA or other government agencies in the event of recalls or the discovery of illegitimate products.
4. The requirement that trading partners have in place systems and processes to allow the acceptance of a saleable returned product by associating that returned, saleable product with its original transaction information and statement.

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