RESOURCES

FDA Issues Guidance on DSCSA Waivers, Exceptions and Exemptions

In May 2018, the FDA published new DSCSA draft guidance "Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act". The recent increase in FDA guidance publication activity could indicate that the FDA is ramping up its efforts to ensure that industry stakeholders have all the information they need to meet the next series of DSCSA deadline without delay.

Summary

This new DSCSA guidance represents the FDA's recommendations for how trading partners and stakeholders should request a waiver, exception or exemption from the requirements of DSCSA. It describes how the FDA intends to review and decide such requests and determine FDA-initiated exceptions and exemptions. It also describes how the FDA intends to review and renew such actions. DSCSA formally provides that the FDA issue guidance establishing processes whereby:

- An authorized manufacturer, repackager, wholesale distributor or pharmacy dispenser may request a waiver from any of the requirements set forth in DSCSA.
- The FDA can determine exceptions, and the process for requesting such exceptions, for a manufacturer or repackager from the product identifier

requirements if a product package is too small or otherwise unable to accommodate a label with sufficient space for the product identifier information.
- The FDA may determine other products or transactions that shall be exempt.

Information that should be provided for a waiver request includes:

- Identity of the trade partner(s)
- Description of the activities/products related to the request
- DSCSA requirements related to the request
- Detailed statement of reasons/rationale for the request
- Requested effective period for the request
- Contact information

The FDA will review the request based on the rationale provided and the potential risks that such a waiver, exception or exemption may pose to the security of the drug supply chain.

- The FDA will notify the requesting party of the Agency's determination. No specific time frame for a response is given.
- The FDA will undertake a biennial review of each request to determine if there has been a material change and whether, as a result, the request is no longer appropriate.
- If a request was of a specific duration, stakeholders may request a renewal.

Note that, in the guidance, different addresses (electronic, paper) are used for CBER-regulated products vs. all other products.

This DSCSA guidance indicates the importance for authorized manufacturers, repackagers, wholesale distributors and pharmacy dispensers to document any situation or scenario that they consider to warrant an exception to the DSCSA requirements. Unless the case for exemption has been made and submitted correctly, it is expected that a product will be subject to enforcement of the DSCSA

labeling requirements.

Download "Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act"

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