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CARES Act Creates and Updates Drug and Medical Device Shortage Requirements

April 09, 2020 | Blog | By

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In response to the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law on March 25, 2020. In addition to the $2 trillion made available for medical countermeasure development, business relief, and other measures, the CARES Act amends the drug shortage reporting requirements and creates new requirements related to medical device shortages. With increased demand for products used to diagnose and treat COVID-19 patients and the stress placed on the manufacturing and delivery of vital products, having more information about drug, drug ingredient, and device shortages is becoming more critical. Below is an assessment of the drug and device shortage provisions contained in the CARES Act.

Amended Drug Shortage Requirements

The CARES Act expands the scope of drug products subject to notification. Previously, drug manufacturers were required to notify the Food and Drug Administration (FDA) of shortages or expected shortages of drugs that are "life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition." Under the new requirements, manufacturers must also now report to FDA shortages or expected shortages of drugs that are "critical to the public health during a public health emergency declared . . . under section 319 of the PHS Act". The term "critical to the public health" will need to be defined by FDA in guidance.

Further, the CARES Act amends drug shortage reporting requirements that were enacted as part of the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA). Per the requirement added by FDASIA, drug manufacturers are required to report anticipated drug shortages to the FDA six months before the discontinuance or interruption of the drug supply or "as soon as practicable." While the timing of the notification has not changed, the contents of the notification were expanded under the CARES Act.

The following items must be included in any drug shortage notification:

- The manufacturer must disclose the shortage of an active pharmaceutical ingredient (API) of a drug product that is "likely to lead to a meaningful disruption in the supply of the [API] of such drug;"
- The manufacturer must provide the reason(s) for the drug shortage. If the drug manufacturer anticipates a shortage of API, it must disclose the course of the API and all alternative sources of the API known to the manufacturer;
- The manufacturer must disclose whether any associated device is the reason for the drug shortage; and
- The manufacturer must disclose the expected duration of the shortage.

Although finished drug products cannot be made without APIs, the inclusion of the API shortages or anticipated shortages is a significant change. In including this provision, Congress hopes that advance notice of shortages for key ingredients will enable the supply chain to react prior to the negative impacts an API shortage may have on the manufacturing of a finished product.

After the CARES Act was enacted, FDA quickly issued **guidance** regarding the notification of a permanent discontinuance or interruption in manufacturing under the Federal Food, Drug, and Cosmetic Act (FD&C Act) Section 506C (21 U.S.C. § 356c). Aside from providing guidance to drug companies of the why, who, when, and how of the drug shortage notification requirements, the guidance also provides answers to what information should be included in the notification. FDA recommends considering the following when providing notification:

- Is this notification for an unavoidable supply disruption or a supply disruption that may be preventable?
- What is the underlying reason or root cause leading to this notification?
- What is the estimated date of onset of the interruption in manufacturing or supply disruption for this product?
- If a supply disruption has occurred, what is the estimated duration?
- If the notification is for a permanent discontinuance, what is the anticipated period for all existing product (on hand and in distribution channels) to be exhausted?
- What is your estimated market share for the product? Is your entire market share affected by this issue? What is the estimated volume of your historic monthly sales, usage, or demand, as applicable, for this product?
- Is this product manufactured on multiple lines or in multiple facilities?
- How much current inventory of product is at your facility or warehouse?

- When will the last batch of finished product be released into distribution? Based on the current demand, how long do you expect the supply to last in the market without additional releases?

In addition, the CARES Act requires all manufacturers of drugs or APIs to "develop, maintain, and implement" a risk management plan that identifies and evaluates the risks to the supply of the drug or API for each establishment in which such drug or API is manufactured. FDA indicated it will be issuing guidance soon, so stay tuned.

Another change to the drug shortages requirements in the CARES Act is that manufacturers must now send FDA an annual report on the quantity of drugs "manufactured, prepared, propagated, compounded, or processed" at registered facilities for commercial distribution.

The CARES Act also mandates that FDA prioritize and expedite the review of an Abbreviated New Drug Application (ANDA) or a supplement to a New Drug Application (NDA) or ANDA that could help mitigate or prevent the drug shortage. Prior to the passage of this provision, Congress *permitted* FDA to do so; however, now it is *mandating* FDA to take quicker action.

New Medical Device Shortage Requirements

The CARES Act also amended the Federal Food, Drug, and Cosmetic Act to mandate manufacturers report medical device shortages to the FDA. This new mandate closely mirrors the shortage requirements for drugs. Manufacturers that must adhere to these new requirements are those that manufacture a device that is either:

- Critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery; or
- For which the Secretary determines that information on potential meaningful supply disruptions of such device is needed during, or in advance of, a public health emergency.

While section 506C of the FD&C Act applied to drugs and biologics, the CARES Act made section 506C applicable to device manufacturers as well. For example, device manufacturers must maintain and implement redundancy risk management plans if the device is used for preparation or administration to a drug product covered by section 506C.

Conclusion

There is no guarantee that these measures will limit or prevent future medical product shortages; however, with more information about confirmed or expected medical product shortages, FDA, other manufacturers of a product experiencing a shortage, or other supply chain partners may be able to take steps to mitigate the effects of the shortage. Given the rapid changes and extreme pressure, the COVID-19 pandemic is having on drug and medical device supply chains, these provisions in the CARES Act are designed to assist FDA in swiftly and adequately responding to shortages during the ongoing public health emergency and in other situations.

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