FDA Issues Guidance on Supply Interruptions and Discontinuance Notification Requirements for Emergency and Life Supporting Drugs

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On April 1, 2020, FDA issued a guidance document instructing companies on how to notify the agency of a permanent discontinuance or interruption of manufacturing of certain products pursuant to Section 506C of the FDCA (21 U.S.C. § 356c). Because of the public health emergency related to COVID-19, the guidance document was issued without prior notice and comment, but FDA intends to revise the guidance within 60 days following the termination of the public health emergency to reflect its review of any comments received on the guidance and the agency's experience with its implementation.

The products covered by the notification requirements of 506C include prescription drugs and biological products (including blood or blood components for transfusion) that are life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition. This includes any such product that is used in emergency medical care or during surgery, but it does not include radiopharmaceutical products or other products designated by the FDA.

Notably, the guidance document does not reflect the amendments to Section 506C that were included in the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), which was enacted on March 7, 2020. For example, the guidance does not discuss the Risk Management Plans required by Section 3112(b) of the CARES Act. The guidance also does not reflect the language that the CARES Act added to Section 506C(a)(1) to specify that the reporting requirement also applies to drugs that are "critical to the public health during a public health emergency."

Below are some of the key takeaways from the guidance:

- Manufacturers should notify FDA "as soon as possible of a permanent discontinuance or interruption in manufacturing that is likely to lead to a meaningful disruption in supply" and the notification should include "specific information about the situation that will allow the Agency to evaluate the situation and determine the appropriate course of action."
- The guidance provides a list of questions for manufacturers to consider answering, including:
    - whether the disruption is unavoidable or preventable,
    - the root cause of the manufacturing delay or disruption,
    - the estimated date of onset and duration of the disruption,
    - the estimated market share affected by the issue,
    - the current inventory levels and expectations regarding how long the existing supply will last based on current demand,
    - whether emergency or reserve supplies for the product are available
    - whether the manufacturer has notified its stakeholders about the actual or potential shortage; and
    - whether there are any proposals for FDA to expedite the availability of the product.
- An applicant should establish a process with any of its relevant contract manufacturers and key suppliers to ensure that the applicant can provide a timely and accurate notification to FDA of a discontinuance or interruption in manufacturing.
- The reporting requirement applies to all manufacturers of covered products (other than blood or blood components intended for

transfusion) regardless of market share.Only applicants that manufacture a significant percentage of the U.S. blood supply are subject to the notification requirements for blood or blood components intended for transfusion.

- A manufacturer should base its assessment of whether a meaningful disruption in supply is likely to occur solely on its own capacity and supply, not on its assumptions regarding its competitors' capacity or marketing demand.
- Manufacturers are recommended to provide updates every 2 weeks on the situation, including the expected timeline for recovery, regardless of whether there has been a change in status.
- Manufacturers are requested (but not required) to notify FDA when they are unable to meet demand for products covered by the notification requirement even in the absence of an interruption in manufacturing.
- FDA urges manufacturers to notify an FDA of an interruption even if it us unsure whether a meaningful disruption is likely to occur so that FDA can monitor the situation.
- Notifications are required to be submitted electronically using the email addresses and portals designated in the guidance document.
- Failure to notify a reportable interruption in manufacturing as soon as practicable may result in a noncompliance letter, which will be posted on FDA's website, unless FDA determines that the noncompliance letter was issued in error or that the manufacturer had a reasonable basis for not notifying the FDA as required.

While the guidance document was issued to help the FDA mitigate shortages of drug products in light of the COVID-19 emergency, the recommendations made and processes implemented in the guidance are intended to assist the FDA more broadly in its mitigation of drug product shortages outside of the current emergency.

Foley Hoag has formed a firm-wide, multi-disciplinary task force dedicated to client matters related to the novel coronavirus (COVID-19). For more guidance on your COVID-19 issues, visit our Resource Page or contact your Foley Hoag attorney.

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