WINSTON & STRAWN LLP

CLIENT ALERT

FDA Issues New Guidance for Reporting on Shortages of Drugs and Biologics

APRIL 2, 2020

The Food & Drug Administration ("FDA") has stated that in response to the declared COVID-19 public health emergency, the agency is working closely with manufacturers of drugs and biologics to ensure that they continue to provide timely notice to the FDA of any permanent discontinuance or interruption of drug or biological product manufacturing. To this end, the FDA has published new guidance for immediate implementation about the importance of these notifications, the manufacturers' timelines for notifying the FDA, and details in the notifications to the agency about the circumstances.

The following stakeholders are covered by the notification requirements:

- applicants with an approved new drug application ("NDA") or approved abbreviated new drug application ("ANDA") for a covered drug product;
- applicants with an approved biologics license application ("BLA") for a covered biological product, other than blood or blood components;
- applicants with an approved BLA for blood or blood components for transfusion, if the applicant is a manufacturer of a significant percentage of the U.S. blood supply; and
- manufacturers of a covered drug product marketed without an approved NDA or ANDA.

Products covered by the notification requirement are prescription drugs and biological products (including blood or blood components for transfusion) that are (1) life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including any such product used in emergency medical care or during surgery; and (2) not radiopharmaceutical drug products or any other products designated by the FDA.

See Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry (March 2020).

The guidance reminds manufacturers that a critical component of preventing or mitigating drug shortages is notifying the FDA as soon as possible of a permanent discontinuance or an interruption in manufacturing that is

likely to lead to a meaningful disruption in supply. The FDA notes that early notifications are the agency's best tool in preempting, or at least mitigating, an unavoidable shortage.

Manufacturers must inform the FDA at least six (6) months in advance of (1) a permanent discontinuance in manufacturing of a product or (2) an interruption in manufacturing of a product that is likely to lead to a meaningful disruption in supply of the product in the United States. ***See section 506C(b) of the Federal Food Drug and Cosmetic Act (FD&C Act); §§ 310.306(b), 314.81(b)(3)(iii)(b)(1), and 600.82(b)(1).*** If six (6) months' advance notice is not possible because the discontinuance or interruption was not reasonably anticipated, the notification must be submitted as soon as practicable thereafter, but in no case later than five (5) business days after the discontinuance or interruption in manufacturing occurs. ***See section 506C(b) of the FD&C Act; §§ 310.306(b), 314.81(b)(3)(iii)(b)(2), and 600.82(b)(2).*** After the initial notification of an interruption in manufacturing, the FDA recommends that manufacturers provide updates every two (2) weeks on the situation, including the expected timeline for recovery, even if the status remains unchanged.

Notifications under section 506C of the FD&C Act are required to include certain information. The FDA, however, recommends that manufacturers provide additional details to the FDA about the circumstances that, if possible, answer the following questions:

> 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 timeframe 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?
>
> Do you have an emergency or reserve supply of this product? Is allocation of supply on hand or your reserve supply an option?
>
> Have you provided, or will you provide, public information for your stakeholders and patients regarding this actual or potential shortage (*e.g.*, Dear Healthcare Provider (DHCP) Letters, supply or shortage information posted on your website)?
>
> Do you have a proposal for FDA to review to expedite availability of your product? What do you think FDA can do to help prevent or mitigate a supply disruption?

The Agency has indicated that manufacturers need not have the answers to all the questions prior to initial notification. Manufacturers are encouraged to provide initial notification as soon as is practicable and supplement information as it becomes available. The FDA also makes clear in the guidance its intent to use this information to assess the situation and take appropriate action, and that the submitted information will not be disclosed except in accordance with applicable disclosure law, which includes restrictions on the release of confidential commercial information and trade secrets. If the FDA determines that a product is in shortage, it will work with manufacturers to confirm the accuracy and appropriateness of information regarding the shortage before posting publicly on the FDA's website.

FDA guidance documents reflect the FDA's current thinking on a subject and are recommendations, not requirements. While this guidance was issued without a prior comment period, the FDA will be accepting public comments on it going forward. This guidance reflects the FDA's intent to assist applicants and manufacturers in providing timely, informative notifications about changes in production of certain drugs and biological products to help the Agency in its efforts to prevent or mitigate disruptions and shortages in the United States as a result of COVID-19.

****

For further information or questions on the new guidance for drugs and biologics shortage reporting, please contact T. Reed Stephens, or your Winston relationship attorney.

View all of our COVID-19 perspectives here. Contact a member of our COVID-19 Legal Task Force here.
4 Min Read

Related Locations

Charlotte | Chicago | Dallas | Houston | Los Angeles | New York | San Francisco | Silicon Valley | Washington, DC

Related Topics

COVID-19 | FDA | Health Care

Related Capabilities

Health Care | Medical Devices

Related Regions

North America

Related Professionals

T. Reed Stephens

© 2024 Winston & Strawn LLP.