

CARES Act Reforms Aim to Prevent Shortages of Critical Medical Products

April 5, 2020

Food, Drugs, and Devices

On March 27, 2020, Congress passed and the President signed into law H.R. 748, the [Coronavirus Aid, Relief, and Economic Security Act](#) (the CARES Act). Recognizing the critical supply chain risks posed by the COVID-19 pandemic, Congress included multiple provisions in the CARES Act that aim to mitigate and prevent future medical product shortages (these provisions are primarily located in Part I of Title III, Subtitle A of the Act). These provisions include notable amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act (PHS Act), as summarized below.

Amendments to FDA’s Drug Shortage Notification Requirements

Section 506C of the FD&C Act requires manufacturers of certain drugs to notify FDA of current or potential product shortages. This requirement is designed to ensure that FDA has information relevant to the Agency’s role in preventing and mitigating drug shortages. FDA recently issued a [guidance document](#) summarizing this requirement and recommending additional steps manufacturers can take to support FDA in preventing and mitigating drug shortages in response to COVID-19. To further enhance FDA’s ability to prevent and mitigate drug shortages, the CARES Act amends the FD&C Act as follows:

- Expanding the scope of products subject to the notification requirement. Section 506C previously applied only to drugs that are “life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition.” As amended, this requirement now also applies to drugs that are “critical to the public health during a public health emergency declared . . . under section 319 of the PHS Act.” It is unclear how FDA will determine whether a drug is “critical to the public health” under this provision, and thus additional guidance from the Agency on this topic will be important.
- Requiring notifications of active pharmaceutical ingredient (API) shortages. Section 506C currently requires manufacturers to notify FDA of a permanent discontinuance or a meaningful interruption in the manufacture of a drug product that is subject to the notification requirement. As amended, section 506C will also require manufacturers to notify FDA when they experience a discontinuance or interruption in the manufacture of an API of a covered drug product.
- Requiring manufacturers to include additional information in their notifications. If an API shortage is the reason for a notification, manufacturers will now be required to include the source of the API and alternative sources of the API known to the manufacturer in their notifications. Manufacturers will also be required to indicate “whether any associated device used for preparation or administration included in the drug is a reason for, or a risk factor in, such discontinuation or interruption.”
- Requiring drug and device manufacturers to develop risk management plans. Manufacturers of drugs subject to the section 506C notification requirement—as well as

manufacturers of APIs and associated medical devices used in the preparation or administration included in the drug—will be required to maintain and implement redundancy risk management plans that identify and evaluate risks to the drug supply for each establishment in which the drug or API is manufactured. These plans will be subject to FDA inspection and copying.

- Requiring that drug manufacturers report manufacturing volumes. An amendment to section 510(j) will require manufacturers to send FDA an annual report on the quantity of drugs manufactured, prepared, propagated, compounded, or processed at registered facilities.
- Mandating that FDA take certain actions to mitigate or prevent shortages. Section 506C(g) currently *permits* FDA to expedite the review of an ANDA or a supplement to an NDA or ANDA that could help mitigate or prevent the drug shortage. The CARES Act amends this section to *mandate* that FDA prioritize and expedite the review of such applications.

In addition to amending section 506C, the CARES Act amends other provisions of the FD&C Act that affect drug manufacturers, including:

- An amendment to section 506E that requires FDA to send a drug shortage report to the Administrator of the Centers for Medicare & Medicaid Services every 90 days.
- An amendment to section 704(b) that requires FDA inspectors to send copies of facility inspection reports to FDA's Drug Shortage Staff for facilities that manufacture drugs that have been on FDA's drug shortage list in the past five years.

The amendments made under this section will become effective 180 days from the enactment of the CARES Act.

We separately provided clients with a [detailed summary](#) of the FDA over-the-counter (OTC) drug reform provisions of the CARES Act.

New Requirements for Medical Device Shortage Notification and Risk Management Plans

While section 506C of the FD&C Act previously applied to manufacturers of certain drug and biologic products, medical device manufacturers should be aware that the CARES Act created new medical device shortage reporting requirements. First, device manufacturers should note that requirements of 506C—to maintain and implement redundancy risk management plans, as described more fully above—apply to manufacturers of devices used for preparation or administration included in a drug covered by section 506C. Second, section 3121 of the CARES Act adds section 506J to the FD&C Act, which now requires that certain medical device manufacturers notify FDA of a permanent discontinuance or interruption in manufacturing that is likely to lead to a meaningful disruption of supply in the U.S. This new section to the FD&C Act closely tracks section 506C for drugs and applies to manufacturers of two categories of devices:

1. Devices that are critical to the 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

2. Devices for which the Secretary of Health and Human Services determines that information on potential meaningful supply disruptions of such device is needed during, or in advance of, a public health emergency.¹

When and How to Notify FDA

Manufacturers are required to notify FDA of a permanent discontinuance or interruption in manufacturing that is likely to lead to a meaningful disruption of supply in the U.S., at least six months in advance of the date of the discontinuance or interruption, or, if that is not possible, as soon as practicable. FDA's website says that notifications of potential shortages can be submitted electronically to the Center for Devices and Radiological Health (CDRH) by email: deviceshortages@fda.hhs.gov or telephone: 1-800-638-2041 ([DICE](#)).

Non-Compliance Letters

If a manufacturer fails to notify FDA in accordance with the mandatory reporting requirements, the Agency will send the manufacturer a noncompliance letter. Manufacturers have 30 days to respond to a noncompliance letter, and FDA will post both the noncompliance letter and the manufacturer's response on the Agency's website within 45 calendar days of sending the noncompliance letter unless FDA determines that it was sent in error or that the manufacturer had a "reasonable basis" for not providing a timely notification.

FDA's Device Shortage List and Prioritization of Inspections / Product Reviews

Upon receiving a notification under this provision, and subject to certain exceptions, FDA will add the device to a publicly-available "device shortage list" similar to the lists it maintains for [drugs](#) and [biologics](#). FDA also is required to prioritize and expedite facility inspections and the review of submissions or notifications that may assist in preventing and/or mitigating a shortage.

Additional Provisions Regarding Medical Product Shortages

Other provisions of the CARES Act aim to prevent medical product shortages, including:

- A requirement that the National Academies of Sciences, Engineering, and Medicine issue a report on the country's medical product supply chain. This report must assess the country's dependence on foreign manufacturers and render recommendations for addressing supply chain vulnerabilities that pose a threat to the public health.
- An amendment to section 319F-2(a)(1) of the PHS Act to add certain medical supplies, including personal protective equipment, to the list of products that should be included in the strategic national stockpile.
- An amendment to section 319F-3(i)(1)(D) of the PHS Act to include "respiratory protective devices" as a "covered countermeasure" eligible for certain liability protections under the PHS Act.

¹ The phrase "public health emergency" in this provision refers to a public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act.

Food, Drugs, and Devices

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drug, and Device Practice:

<u>Wade Ackerman</u>	+1 424 332 4763	ackermanw@cov.com
<u>Thomas Cosgrove</u>	+1 202 662 5260	tcosgrove@cov.com
<u>Paula Katz</u>	+1 202 662 5050	pkatz@cov.com
<u>Kathryn Culver</u>	+1 424 332 4773	kculver@cov.com
<u>Cory Trio</u>	+1 202 662 5181	ctrio@cov.com

* * *

To best advise our clients on the rapidly evolving public health situation in the U.S., our [COVID19 task force](#) is staying abreast of daily developments and tracking the latest federal, state, and local policies related to COVID-19.

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP, an international law firm, provides corporate, litigation and regulatory expertise to enable clients to achieve their goals. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.