



## Drug Shortage Guidance

Updated 6/2/2022

Due to supply chain issues, hospitals, clinics, and other healthcare facilities may experience shortages of drugs necessary to care for patients. The Board of Pharmacy has developed the following guidance to assist licensees in obtaining drugs that may not be commercially available from manufacturers or wholesalers.

For questions regarding this guidance, the most expedient way to have your questions answered is to e-mail the Board by visiting: [www.pharmacy.ohio.gov/contact](http://www.pharmacy.ohio.gov/contact).

### **Drug Shortages**

Manufacturers provide the FDA with most of the drug shortage information. You can obtain information on reported drug shortages by visiting the FDA's website, including expected production date and extended use dates: <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>

### **Outsourcing Facilities**

Outsourcing facilities are Ohio-licensed businesses that are registered by the U.S. Food and Drug Administration (FDA) to compound sterile and non-sterile drugs for sale to hospitals, physicians, clinics, or other healthcare facilities.

According to the FDA, outsourcing facilities are authorized to compound any drug that is on the FDA's [drug shortage list](#). Specifically, the agency states:

*The agency also does not consider a compounded drug produced by an outsourcing facility as "essentially a copy" if it is identical or nearly identical to an FDA-approved drug that is on FDA's [drug shortage list](#). The agency also does not intend to take action under this provision if the facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.*

A terminal distributor of dangerous drugs (or any prescriber who is [exempt](#) from licensure) is permitted to buy compounded drugs, including those on the FDA’s drug shortage list (or that have been discontinued or no longer marketed), from an outsourcing facility currently licensed by the Board of Pharmacy (a list of currently licensed outsourcing facilities is available at the end of this document).

A licensee may also verify the licensure of an outsourcing facility by searching Ohio’s eLicense website: [https://elicense.ohio.gov/OH\\_HomePage](https://elicense.ohio.gov/OH_HomePage)

All FDA registered outsourcing facilities are listed on the FDA’s website: <https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities>

### **How to Locate an Outsourcing Facility Producing Drugs in Shortage**

Outsourcing facilities are required to provide FDA with a list of drugs they compounded during the previous six-month period upon initial registration and in June and December each year. This [database](#) contains information reported to FDA within the last three years (last six reporting periods). This information may be used to identify outsourcing facilities that have produced certain drugs that are currently in shortage.

To access the FDA Outsourcing Facility Product Report, visit: <https://www.accessdata.fda.gov/scripts/cder/outsourcingfacility/index.cfm>

**NOTE:** This retrospective information does not identify drugs that outsourcing facilities intend to produce in the future.

Outsourcing Facility Product Report						
<a href="#">f SHARE</a> <a href="#">TWEET</a> <a href="#">LINKEDIN</a> <a href="#">PIN IT</a> <a href="#">EMAIL</a> <a href="#">PRINT</a>						
Current through June 01, 2022						
You have searched for Active Ingredients: 'Lidocaine'						
<a href="#">Back to Search Page</a>						
Show 10 rows		CSV		Search for text in the table: <input type="text"/>		
Active Ingredients	Active Ingredients Info	Dosage	Estab. Name	Package Description	NDC Package Code	Report Year
Lidocaine	9 mg/1 mL	injection, solution	PROVIDENCE INFUSION HOSPITAL SERVICES(079990088)	3 MI in 1 Syringe, Plastic	-	2021-2
Lidocaine	10 mg/1 mL	injection, solution	Edge Pharma LLC(079514018)	10 MI in 1 Syringe (5446-0850-10)	5446-0850-10	2021-2
Lidocaine	20 mg/1 mL	injection	Wells Pharma of Houston(055774114)	5 MI in 1 Syringe (73702-111-15)	73702-111-15	2021-2
Lidocaine	20 mg/1 mL	injection, solution	STASKA PHARMACEUTICALS, INC (099939403)	10 MI in 1 Syringe (80098-016-01)	80098-016-01	2021-2
Lidocaine	10 mg/1 mL	injection, solution	STASKA PHARMACEUTICALS, INC (099939403)	10 MI in 1 Syringe (80098-005-01)	80098-005-01	2021-2

*Sample Outsourcing Facility Report for Lidocaine*