

Contrasting the FDA (CDER) and ASHP Drug Shortage Websites: What are the differences?

	FDA	ASHP
Purpose	Provides information obtained from manufacturers about current shortages, estimated duration, and discontinuations and provides information about FDA's and other stakeholders' roles in addressing and preventing shortages	Notification of new shortages and status of ongoing shortages; drug shortage management resources
Audience	Public	Healthcare practitioners
Scope of shortage list	All drugs are listed that are confirmed to be a national shortage by FDA. A shortage is considered to be the period of time when the demand for the drug within the United States exceeds the supply of the drug. Note: A separate shortage webpageⁱ for vaccines and some biologics is maintained by the Center for Biologics Evaluation and Research.	All drug and biologic shortages reported and confirmed with manufacturer that are national in impact. Note: ASHP frequently lists more shortages than FDA.
Source of shortage report	Manufacturers notify FDA of production disruption and voluntarily provided updates. Reports are also received from ASHP and from public via drugshortages@cder.fda.gov Note: Manufacturer-provided information represents shortage status at drug firm level	Voluntary reports from practitioners, patients, pharmaceutical industry representatives and others Note 1: Information is updated based on release dates from manufacturers. Note 2: Reports reflect status at healthcare provider level.
Criteria for inclusion on list	Manufacturers cannot meet current market demand for the drug based on information provided by manufacturers and market sales research	(1) Shortage is verified with manufacturers and (2) affects how pharmacy prepares or dispenses a product, or (3) requires use of alternative drugs, which may affect patient care
Criteria for resolving shortage	One or more manufacturers are in production and able to meet full market demand	All manufacturers of the drug restore all formulations and dosage sizes to full availability. Note: Product are listed despite partial or restricted availability as supply chain disruptions can result in intermittent shortages at the provider or patient level
Reason for shortage	Provided by manufacturers using reasons required by legislation. ⁱⁱ FDA encourages firms to provide additional information about reasons and other information which, if proprietary, is nondisclosable without the firms' permission.	Provided by manufacturer, if willing to disclose. Note: May differ from FDA's due to different sources of information and legislation requiring FDA to use specified reasons
Other information	Estimated duration, links to regulatory information such as recalls and Dear Healthcare Provider Letters	Estimated duration, list of available products, implications for patient care and safety, shortage management strategies, therapeutic alternatives

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ⁱ URL : <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/ucm351921.htm>

ⁱⁱ From the [Food and Drug Administration Safety and Innovation Act](#). 2012. A reason selected from the following categories must be provided for each drug on the shortage list: (a) Requirements related to complying with good manufacturing practices (b) Regulatory delay (c) Shortage of an active ingredient (d) Shortage of an inactive ingredient component (e) Discontinuation of the manufacture of the drug (f) Delay in shipping of the drug (g) Demand increase for the drug.